From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Wed, 16 Oct 2013 01:38:34 +0000

To: Ringel Michael; Cairns-Smith Sarah (b) (6); Palisch Chase

(b) (6)

Subject: Coming up for air?

Hi Michael, Sarah, and Chase,

It looks hopeful that the shutdown will not last more than another few days (though that's far from certain).

(b) (5). Though my Institute Director colleagues are furloughed and unable to join TVC discussions until after the shutdown ends, as a Presidential appointee
(b) (5). Would it be worth pulling a few of us (pharma, BCG, FNIH, me) together on Friday AM to see where we are and lay out some of the next steps?

Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 30 Aug 2013 17:56:09 +0000

To: Palisch Chase (b) (6)
Cc: Ringel Michael (b) (6)

Subject: current version of white papers

Chase, can you send me the current versions of all four white papers? And also the most recent version of the pitch deck. I want to be sure I'm using the right ones.

FC

| From:<br>Sent:                                                                                  | Collins, Francis (NIH/OD) [E]<br>Tue, 30 Jul 2013 19:14:28 +0000                                                  |                                 |             |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------|
| To:                                                                                             | Carter, Robert (NIH/NIAMS) [E]                                                                                    |                                 |             |
| Cc:                                                                                             | Ringel Michael                                                                                                    | (b) (6)                         |             |
| Subject:                                                                                        | FW: Inquiry on TVC                                                                                                |                                 |             |
|                                                                                                 |                                                                                                                   |                                 |             |
| Hi Bob,                                                                                         |                                                                                                                   |                                 |             |
| See note below from                                                                             |                                                                                                                   | (b) (                           | 5) Can you  |
| suggest responses for n                                                                         | ne to share with Rick?                                                                                            |                                 |             |
| Thanks, Francis                                                                                 |                                                                                                                   |                                 |             |
| From: Lifton, Richard [ Sent: Tuesday, July 30 To: Collins, Francis (NII Subject: Inquiry on TV | H/OD) [E]                                                                                                         |                                 |             |
| Dear Francis,                                                                                   |                                                                                                                   |                                 |             |
| I received the inquiry                                                                          | below from                                                                                                        | (b                              | 9) (4)      |
| Best-                                                                                           |                                                                                                                   |                                 |             |
| Rick                                                                                            |                                                                                                                   |                                 |             |
|                                                                                                 |                                                                                                                   |                                 |             |
| Rick,                                                                                           |                                                                                                                   |                                 |             |
| regarding participatio                                                                          | we been asked to make a recomm<br>n in the target validation consort<br>d was hoping to get five minutes<br>tion. | ium. Looked like you have a sen | ior role in |
| I'm positive on the R.                                                                          | A / SLE projects with two caveat                                                                                  | ts:                             |             |

(b) (4)

If email doesn't work we can talk this week. I'll peel myself out of whatever meeting I'm in to have this discussion.

Thanks,

Mark

Mark E. Curran, Ph.D.
Vice President, Immunology
Systems Pharmacology & Biomarkers
Janssen Research & Development
Immunology Therapeutic Area
1400 McKean Road
Springhouse, PA 19477

Tel: 215.793.7559

Mobile: (b) (6)

Mcurran3@its.jnj.com

From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 12 Dec 2013 10:08:04 +0000

To: Ringel Michael (b) (6)

Subject: FW: Lawrence Livermore

Hi Michael,

See comments below from Austin, Green, and Phil Bourne (newly announced Associate Director for Data Science at NIH, arriving in February). Please work through Chris for follow ups.

Best, Francis

**From:** Austin, Christopher (NIH/NCATS) [E] **Sent:** Wednesday, December 11, 2013 4:04 PM

To: Green, Eric (NIH/NHGRI) [E]; 'Bourne, Phil'; Collins, Francis (NIH/OD) [E]

Subject: RE: Lawrence Livermore

I met briefly with Jason Paragas in October, and certainly there are areas of shared interest from a systems, pharmacology, chemical genomics, and informatics POV. (b) (5)

actually envisions doing, but this could be the subject of conversations between our groups. Glad to be point person with LLNL on this as desired. Chris

From: Green, Eric (NIH/NHGRI) [E]

Sent: Wednesday, December 11, 2013 3:43 PM

To: 'Bourne, Phil'; Collins, Francis (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]

Subject: RE: Lawrence Livermore

I am not sure I have much to add beyond what Phil said.

These are all important areas, but on a practical level, I can't quite tell what sort of NIH-Livermore interactions they are envisioning.

Eric

Eric Green, M.D., Ph.D.
Director, National Human Genome Research Institute
Acting Associate Director for Data Science
National Institutes of Health
31 Center Dr.
Bldg. 31, Rm. 4B09
Bethesda, MD 20892-2152

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E-Mail: (b) (6)

Web: genome.gov/Staff/Director

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See unlockinglifescode.org for details

From: Bourne, Phil [mailto:bourne@sdsc.edu]
Sent: Wednesday, December 11, 2013 2:54 PM

To: Collins, Francis (NIH/OD) [E]; Bourne, Phil; Green, Eric (NIH/NHGRI) [E]; Austin, Christopher

(NIH/NCATS) [E]

Subject: Re: Lawrence Livermore

Hi Francis:

I do not have much of a context for this discussion, so I may be off-base, but my thoughts are as follows. These are four very important areas and in principle very worth pursuing. However, the complexity of each will require expertise in-house as well as through close collaborators. The immediate bottleneck to progress will not be compute resources, but expertise. My experience where the majority of scientific expertise is isolated from the computational expertise has not been good. True synergy is needed by the two sets of experts working side by side.

|           | (b) (4 <sub>1</sub> |
|-----------|---------------------|
|           |                     |
|           |                     |
|           |                     |
|           |                     |
|           |                     |
| Best/Phil |                     |

From: <Collins>, "Collins, Francis (NIH/OD) [E]" (b) (6)

Date: Tuesday, December 10, 2013 3:02 PM

To: Philip Bourne < Bourne@sdsc.edu >, "Green, Eric (NIH/NHGRI) [E]" (b) (6) "Austin,

Christopher (NIH/NCATS) [E]" (b) (6)

Subject: FW: Lawrence Livermore

Hi Phil, Eric, and Chris,

See note below from Michael Ringel of BCG, with whom I have been working as part of the development of the Target Validation Consortium (which aims to launch in January).

Can I get your thoughts on this Lawrence Livermore initiative, and what the next steps should be?

#### Francis

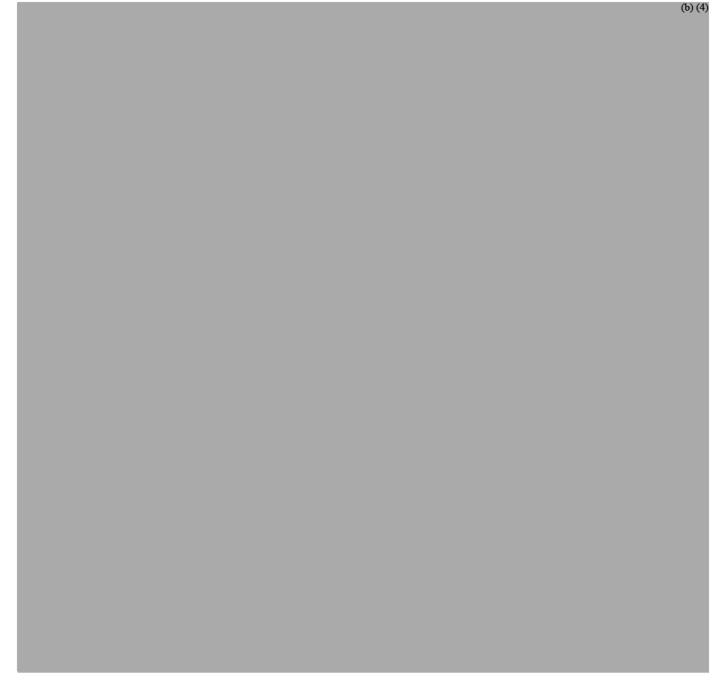
From: Ringel Michael [mailto (b) (6)

Sent: Tuesday, December 10, 2013 8:57 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Lawrence Livermore

Francis,

I hope you are doing well. How did the discussion of AMP go yesterday?



#### All best, Michael

| Michael    | Ringel, Ph.D.                                                       |         |
|------------|---------------------------------------------------------------------|---------|
| Partner ar | nd Managing Director                                                |         |
| Exchange   | TON CONSULTING GRO<br>Place, 31st floor<br>assachusetts 02109 • Uni |         |
| Tel.       | (b) (6) • Mobile (b) (6)                                            | (b) (6) |
| Assistant  | : Lindsey Mastroianni                                               |         |
|            | (b) (6) *                                                           | (b) (6) |

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From: Collins, Francis (NIH/OD) [E]
Sent: Tue, 29 Oct 2013 19:47:00 +0000

To: Wholley, David (FNIH) [T]

Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6)
(b); Palisch Chase (b) (6); Hudson, Kathy (NIH/OD) [E]

Subject: FW: PhRMA and TVC

Hi David,

I just realized I wasn't certain how the loop was to be closed with (b) (5)

FC

----Original Message----

From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Friday, October 25, 2013 5:51 PM

To: Collins, Francis (NIH/OD) [E]

(NIH/OD) [E]

Subject: Re: PhRMA and TVC

I am fine Mikael

**From:** Jan Lundberg [mailto:lundberg\_jan@lilly.com]

Sent: Saturday, October 26, 2013 6:38 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: PhRMA and TVC

Ok with me

Best Jan

Skickat från min iPhone

Oct 25, 2013 kl. 4:45 PM skrev "Collins, Francis (NIH/OD) [E]" (b) (6)

Hi Mikael and Jan,

Francis Cuss just called me to report on the interactions that you three have been having about the possibility of PhRMA playing some role in the TVC. I understand that there are some reservations about how useful this would be, given the history – but I am not hearing that there are major negatives. From an optics perspective, and perhaps on the chance that the PhRMA SLAC actually turns out to be a useful venue for collaborative ventures, I think it would be appropriate to invite their participation at the dollar

figure already proposed. We could then add Bill Chin to the Extended Steering Committee (not the Executive Committee).

Francis Cuss is OK with that plan. But I want to be sure that you two are also. If either of you have objections, please let me know in the next 24 hours or so.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Tue, 20 Aug 2013 16:08:44 +0000

To: Cairns-Smith Sarah (b) (6);Ringel Michael

(b) (6)

Subject: FW (b) (5)

(b) (5)

----Original Message----

From: David Altshuler [mailto:altshul@breadinstitute.org]

Sent: Friday, August 16, 2013 8:30 AM

To: Cairns-Smith Sarah; Collins, Francis (NIH/OD) [E]

Subject: (b) (4)

You can cc me and say I suggested the contact. (Eisai has four scientific advisors who work closely with the CEO, so more relevant to mention than in most advisory settings)

(b) (4)

Potential interest in AD (primary) and Lupus (secondary). No activity in T2D or SCZ, so less relevant.

Best,

David

From: Collins, Francis (NIH/OD) [E]
Sent: Tue, 24 Sep 2013 13:41:02 +0000

To: Ringel Michael (b) (6) Cairns-Smith Sarah (b) (6)

;Palisch Chase (b) (6)

Subject: FW: Target Validation Call

Sigh. It was worth a try.

From: Traci Carrithers [mailto:Traci.Carrithers@gilead.com] On Behalf Of Norbert Bischofberger

Sent: Monday, September 23, 2013 3:12 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** RE: Target Validation Call

Dear Francis,

Thank you for the opportunity to participate in this consortium. We have discussed internally and I regret to say that we have decided to decline. The reason being is that the four chosen therapeutic areas fall outside our immediate research area and focus. If that should in any way change I the future, I will contact you to see if there is a still an opportunity.

Thank you again, Norbert

From: Collins, Francis (NIH/OD) [E] [mailto (b) (6)

Sent: Monday, August 19, 2013 1:37 PM

To: Norbert Bischofberger

Cc: Traci Carrithers; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Ringel Michael

(b) (6) Cairns-Smith Sarah (b) (6)

Subject: RE: Target Validation Call

Hi Norbert,

It was a pleasure to speak with you earlier today. Attached is a ppt file that provides details of the current Target Validation Consortium plan. I would be glad to answer further questions about this, as would my industry colleagues Dolsten, Lundberg, or Cuss. It would be great to have Gilead as a participant in one or more of these projects.

Best regards, Francis

From: Collins, Francis (NIH/OD) [E] Sent: Friday, August 16, 2013 4:39 PM To: 'nbischofberger@qilead.com'

Cc: 'Traci.Carrithers@gilead.com'; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

Subject: Target Validation Call

Dear Norbert,

As you know, the Target Validation Consortium recently brought together leading academics and industry representatives to develop detailed research plans in four disease areas. We are enthusiastic that the proposals will help us find more efficient routes to validate drug targets, reversing the current trend of costly late-stage failures.

I am happy to announce that the NIH is pledging significant support for each project across all disease areas. We have committed to funding 50% of the total research costs and have the full support of the Directors of NIMH, NIA, NIDDK, NIAMS, and NIAID.

I would like to briefly discuss this with you early next week; I don't expect the phone call to take more than 10 minutes. Please have your assistant contact Gretchen or Ayanna to schedule a convenient time to chat.

I look forward to hearing from you soon.

Best regards, Francis From: Collins, Francis (NIH/OD) [E]
Sent: Tue, 13 Aug 2013 03:32:47 +0000

To: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

Subject: FW: Target Validation Check-in

Attachments: August 09 2013 TV SC Meeting Summary and Action Items vFinal.docx, TVC -

Outreach contacts - Francis Collins - 130802.xlsx

Note that I've agreed to 15 minute phone calls with John Reed and Jim Sullivan. Contact info was in a previous e-mail from BCG, reattached here. John Reed had responded previously to say he was on vacation but would be glad to talk. We haven't tried to reach Sullivan previously.

Tx, FC

From: Palisch Chase [mailto (b) (6)

Sent: Monday, August 12, 2013 11:34 AM

To: Ringel Michael; Holt, Tracy (NIH/NIMH) [E]; Wagner, Tim; 'altshuler@molbio.mgh.harvard.edu'; Carter, Robert (NIH/NIAMS) [E]; Budzinack, Janet; Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Bronson, Charlette (NIH/NIA) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; 'francis.cuss@bms.com'; Stefan Reed; Meltzer, Sherry (NIH/NIAMS) [E]; debra.zander@bms.com; Schulke, Hilda (NIH/OD) [E]; 'mikael.dolsten@pfizer.com'; Insel, Thomas (NIH/NIMH) [E]; edmonds\_pamela\_j@lilly.com; Hodes, Richard (NIH/NIA) [E]; Cairns-Smith Sarah; Collins, Francis (NIH/OD) [E]; 'garry@appletreepartners.com'; 'richard.lifton@yale.edu'; Bloom (Sartorius) Leah; Katz, Stephen I. (NIH/NIAMS) [E]; Sara Ponzo; Hudson, Kathy (NIH/OD) [E]; Brawley, David (NIH/NIDDK) [E]; 'lundberg\_jan@lilly.com'

Subject: RE: Target Validation Check-in

Dear colleagues,

Attached you will find the notes from Friday's meeting. In addition, below is the current status and next steps for outreach to high priority industry members.

Please take a look at the list of potential members and let us know if you would be willing to reach out to any of the internal contacts to discuss the TVC. We can then coordinate the meetings and provide any contact details necessary.

Please let us know if you have any questions.

Thanks,

Chase & the BCG team

(b) (4)



Chase Palisch
THE BOSTON CONSULTING GROUP
Tel. (b) (6) \* Mobile (b) (6)

```
----Original Appointment----
From: Ringel Michael
Sent: Thursday, June 20, 2013 12:24 PM
To: Ringel Michael; Palisch Chase;
                                                (b) (6); Wagner, Tim;
'altshuler@molbio.mgh.harvard.edu';
                                                       (b) (6); Chand Nikhilesh;
Budzinack, Janet; 'Wood, Gretchen (NIH/OD) [E]'; 'dwholley@fnih.org';
                   (b) (6)
                                                (b) (6) 'francis.cuss@bms.com'; Stefan
                             (b) (6); debra.zander@bms.com;
Reed:
'mikael.dolsten@pfizer.com';
                                           (b) (6); edmonds pamela j@lilly.com;
                   (b) (6) Cairns-Smith Sarah;
'garry@appletreepartners.com'; 'richard.lifton@yale.edu'; Bloom (Sartorius) Leah;
                                                         (b) (6) Fortune Jennifer;
                   (b) (6); Sara Ponzo;
                   (b) (6) 'lundberg jan@lilly.com'
Cc: Piccin, David; 'Wendy Ward'
Subject: FW: Target Validation Check-in
When: Friday, August 02, 2013 8:00 AM-8:30 AM (UTC-05:00) Eastern Time (US &
Canada).
Where: ID:
                    (b) (6), Phone:
                                            (b)(6)
```

When: Occurs every Friday effective 2/1/2013 until 8/30/2013 from 8:00 AM to 8:30 AM (UTC-05:00) Eastern Time (US & Canada).

| Where: ID:        | (b) (б), Phone:                                 | (b) (6)                                                                   |      |
|-------------------|-------------------------------------------------|---------------------------------------------------------------------------|------|
| Note: The GMT     | offset above does not                           | reflect daylight saving time adjustments.                                 |      |
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|                   |                                                 |                                                                           |      |
| Original App      |                                                 |                                                                           |      |
| From: Ringel Mi   |                                                 | .17 DM                                                                    |      |
| To:               | ay, March 13, 2013 12<br>Wagner, Tim            | ; 'altshuler@molbio.mgh.harvard.edu';                                     |      |
| ь                 |                                                 | esh; Budzinack, Janet; 'Wood, Gretchen (NIH/O                             | ))   |
| [E]'; 'dwholley@  | fnih.org'; '                                    | (b) (6)                                                                   | 10   |
|                   | ns.com'; Stefan Reed;                           |                                                                           |      |
| debra.zander@b    | ms.com;<br>o)(6); <u>edmonds_pamel</u>          | (b) (6); 'mikael.dolsten@pfizer.com';<br>a j@lilly.com; (b) (6)'; Cairns- |      |
| Smith Sarah;      |                                                 | a jumy.com, cams-<br>erry@appletreepartners.com';                         |      |
|                   | ale.edu'; Bloom (Sarto                          |                                                                           | 0;   |
|                   | (b) (6) Fortune Jenn                            |                                                                           | 32   |
| 'lundberg_jan@li  |                                                 |                                                                           |      |
| Cc: Piccin, David |                                                 |                                                                           |      |
|                   | Validation Check-in                             | 2/1/2013 until 8/30/2013 from 8:00 AM to 8:30 A                           | ΔM   |
|                   | tern Time (US & Cana                            |                                                                           | XI-1 |
| Where: ID:        | (b) (6), Phone:                                 | (b) (6)                                                                   |      |
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| Note: The GMT o   | offset above does not                           | reflect daylight saving time adjustments.                                 |      |
| *~*~*~*~*         | ·*~*~*                                          |                                                                           |      |
| 6/13 - extending  | the Friday TVC chec                             | k-ins through August.                                                     |      |
| ******            | ******                                          | *************                                                             | ***  |
| *****             | ****                                            |                                                                           |      |
| Mobile phone lin  | k:                                              | (b) (6)                                                                   |      |
| Blackberry quick  | dial-in:                                        | (b) (6)#                                                                  |      |
| iPhone quick dia  |                                                 | (b) (6)#                                                                  |      |
| Passcode          | (b) (6)                                         |                                                                           |      |
| To manually atte  | nd the Voice Confere                            | nce:                                                                      |      |
| 1. Dial in        | to MeetMe (In-office s<br>he Passcode followed  | peed dial: (b)(6))                                                        |      |

#### Important commands

Operator assistance (also in case of quality issues) Conference help menu \*0

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## Global Access Numbers & Additional commands (b) (6)

#### Dial-in Numbers:

Norway

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|--------------------------------|---------------------------------------------------------------------------------------------------------------|
| Country                        | Number                                                                                                        |
| Argentina                      | +54 1153541176                                                                                                |
| Australia                      | +61 280318145                                                                                                 |
| Austria                        | +43 1206091303                                                                                                |
| Bahrain                        | 80004629                                                                                                      |
| Belgium                        | +32 22008540                                                                                                  |
| Brazil                         | +55 11 4700 1524                                                                                              |
| Brazil (Toll-free)             | 08000474988                                                                                                   |
| Canada                         | +18774826140                                                                                                  |
| Chile (Toll-free)              | 800395032                                                                                                     |
| China                          | +86 4008811648                                                                                                |
| China (Beijing)                | +86 10 8527 9944                                                                                              |
| China (Shanghai)               | +86 21 2306 4005                                                                                              |
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| Croatia (Toll-free)            | 0800777982                                                                                                    |
| Cyprus (Toll-free)             | +357 800 924 67                                                                                               |
| Czech Republic                 | +420 239016131                                                                                                |
| Denmark                        | +45 43682373                                                                                                  |
| Dominica (Toll-free)           | +767 1800 988 7777                                                                                            |
| Dominican Republic (Toll-free) | +809 188 849 16 882                                                                                           |
| Finland                        | +358 972519406                                                                                                |
| France (English Greeting)      | +33 157323421                                                                                                 |
| France (French Greeting)       | +33 157324152                                                                                                 |
| Germany                        | +49 69380789012                                                                                               |
| Greece                         | +30 210 7260 366                                                                                              |
| Hong Kong                      | 800966116                                                                                                     |
| Hungary                        | +36 17774899                                                                                                  |
| Iceland (Toll-free)            | 8008867                                                                                                       |
| India (Mumbai)                 | +91 22 6749 7556                                                                                              |
| India (New Delhi)              | +91 124 459 7456                                                                                              |
| Indonesia                      | +62 21 3006 2829                                                                                              |
| Ireland                        | +353 14073041                                                                                                 |
| Israel (Toll-free)             | 1809440298                                                                                                    |
| Italy                          | +39 0291483822                                                                                                |
| Jamaica (Toll-free)            | 18009883086                                                                                                   |
| Japan                          | +81 332984074                                                                                                 |
| Japan (Toll-free)              | 0120 995 200                                                                                                  |
| Latvia (Toll-free)             | 80004602                                                                                                      |
| Lithuania (Toll-free)          | 880031646                                                                                                     |
| Luxembourg                     | +352 24871300                                                                                                 |
| Malaysia                       | +60 362074380                                                                                                 |
| Mexico (Mexico City)           | +52 55 5258 9890                                                                                              |
| Mexico (Monterrey)             | +52 81 8368 6290                                                                                              |
| Netherlands                    | +31 202035001                                                                                                 |
| New Zealand                    | +64 99123620                                                                                                  |
|                                |                                                                                                               |

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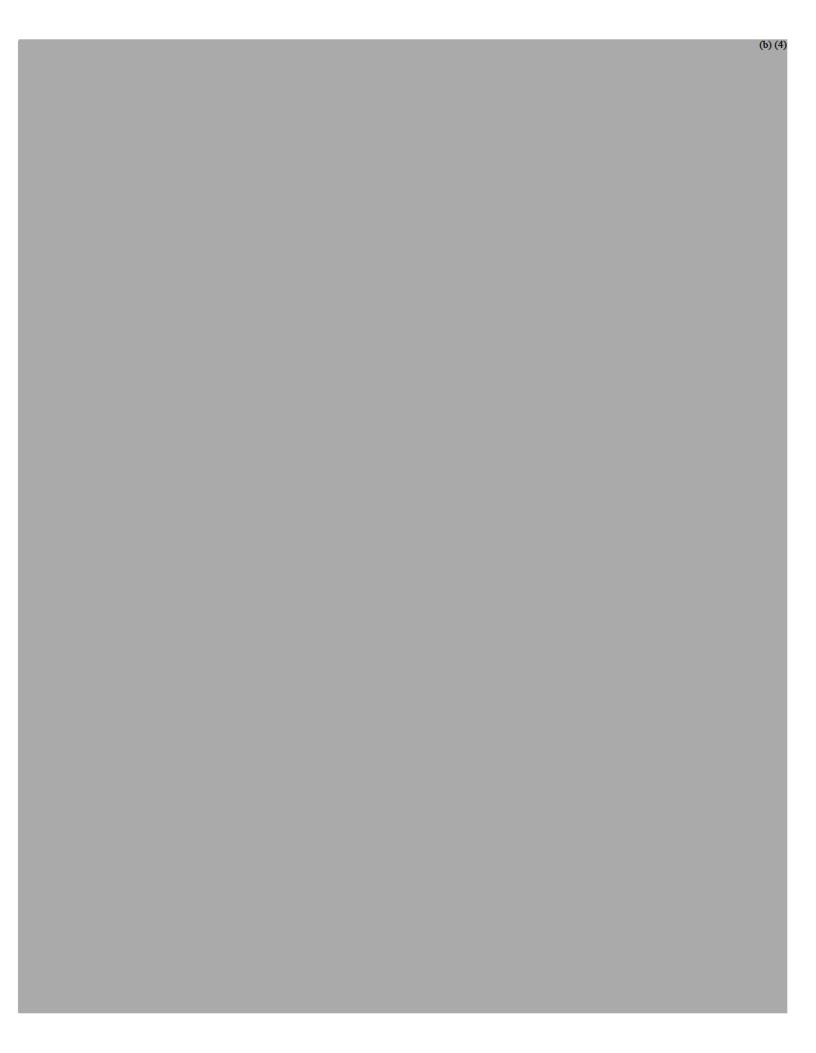
Trinidad and Tobago +868 188 820 16 992
Turkey (LandLine only Toll-free) 00800448823970
Ukraine +380 44 495 95 92
Ukraine (Toll-free) 0800502179
United Arab Emirates 80004440049
United Kingdom +44 2030279674
United States +17203627740

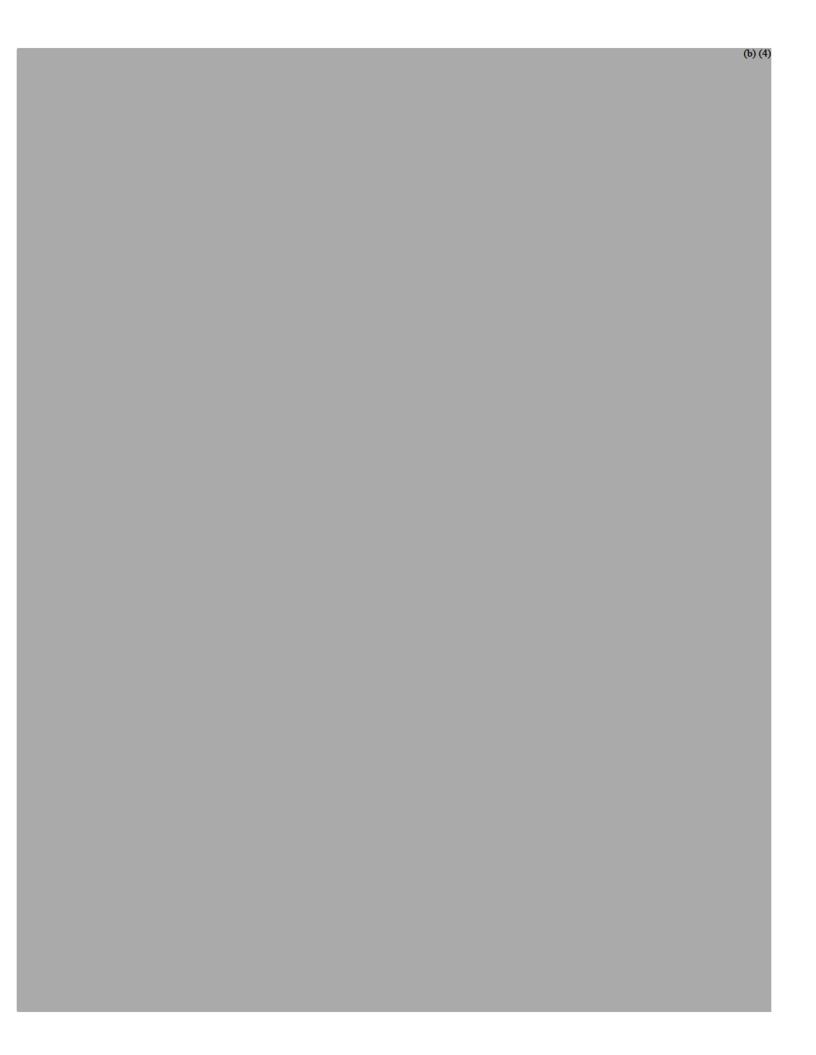
United States +17203627740 United States (Toll-free) +18774826140 Venezuela (Toll-free) +58 80 010 08 672

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| (b) (4) |
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|         |

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Tue, 1 Oct 2013 04:02:39 +0000

To: Palisch Chase (b) (6)

Subject: FW: Target Validation Consortium

**From:** Daniel Rader [mailto:rader@mail.med.upenn.edu]

Sent: Monday, September 30, 2013 11:50 PM

To: Collins, Francis (NIH/OD) [E]; Rodgers, Griffin (NIH/NIDDK) [E]

Subject: Re: Target Validation Consortium

Dear Dr Collins and Dr Rodgers-

I would be happy to participate in this process but unfortunately am unavailable on Oct 2.

If you need to reschedule due to a govt shutdown, please let me know and I will be pleased to participate if possible

Best, Dan Rader

On 9/25/13 10:28 AM, Collins, Francis (NIH/OD) [E] wrote: Dear Dr. Rader.

The Target Validation Consortium is in the process of finalizing outreach to potential industry participants. Thanks to your efforts, we have had broad industry support to date with eleven companies already pledging support and a further six companies who have indicated interest but have not yet committed.

On October 2nd, we will hold a meeting with all participating companies to kick-off the next phase of TVC efforts, the primary activity of which will be having the participating companies make any necessary revisions to the research plans before issuing RFPs.

To prevent any conflicts of interest, we wanted to notify you that if you participate in this phase of revising the research plans, you will not be allowed to submit proposals to execute the research.

Could you please follow-up with your Technical Group liaison (listed below), indicating whether or not you would like to be recused from this phase of work, in order to maintain flexibility to respond to RFPs? He is available to discuss the pros and cons in more detail, as desired.

Thank you again for all of your efforts in developing the proposals thus far.

Best regards,

Francis S. Collins, MD, PhD Director, National Institutes of Health

#### Technical group liaisons:

Alzheimer's disease: Richard Hodes,
Type 2 Diabetes: Griffin Rodgers,
RA, SLE & related: Bob Carter,
(b) (6)

----

Daniel J. Rader, MD
Cooper-McLure Professor of Medicine and Pharmacology
Chief, Division of Translational Medicine and Human Genetics
Associate Director, Institute for Translational Medicine and Therapeutics
Perelman School of Medicine at the University of Pennsylvania
11-125 Translational Research Center
3400 Civic Center Blvd, Building 421
Philadelphia, PA 19104-5158

Tel (office): 215-573-4176
Fax (office): 215-573-8606
Tel (clinic): 215-615-8659
email: rader@mail.med.upenn.edu

From: Collins, Francis (NIH/OD) [E]

Sent: Thu, 24 Oct 2013 19:05:39 +0000

To: Hudson, Kathy (NIH/OD) [E]

Subject: FW: TVC Check-in Call

Attachments: NIH TVC-Core check-in - 131025 - vFinal.pptx

Is the timing of the project management transition from BCG to FNIH clear to you?

From: Palisch Chase [mailto (b) (6)

Sent: Thursday, October 24, 2013 1:24 PM

To: Ringel Michael; Hodes, Richard (NIH/NIA) [E]; 'lundberg\_jan@lilly.com'; Collins, Francis

(NIH/OD) [E]; Carter, Robert (NIH/NIAMS) [E]; Hudson, Kathy (NIH/OD) [E];

'francis.cuss@bms.com'; 'richard.lifton@yale.edu'; 'mikael.dolsten@pfizer.com'; Rodgers, Griffin (NIH/NIDDK) [E]; Cairns-Smith Sarah; Wholley, David (FNIH) [T]; Insel, Thomas (NIH/NIMH) [E]; Katz, Stephen I. (NIH/NIAMS) [E]

Cc: elizabeth.cappello@yale.edu; Schulke, Hilda (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Bronson, Charlette (NIH/NIA) [E]; Holt, Tracy (NIH/NIMH) [E]; Meltzer, Sherry (NIH/NIAMS)

[E]; Wood, Gretchen (NIH/OD) [E] **Subject:** RE: TVC Check-in Call

Hi everyone,

We wanted to remind you all that we have a Target Validation Consortium check-in scheduled for tomorrow morning from 8:00-8:30am. Attached you will find materials for tomorrow's meeting which outlines the next steps for revising the proposals as well as the proposed governance and membership for the next phase.

We look forward to connecting tomorrow. Please let us know if you have any questions in the meantime.

Thanks,
Chase

Chase Palisch
THE BOSTON CONSULTING GROUP
Tel. (b) (6) - Mobile + (b) (6)

----Original Appointment-----From: Ringel Michael

Sent: Monday, October 21, 2013 4:28 PM

To: (b) (6); 'lundberg\_jan@lilly.com'; (b) (6) (6) (7); 'francis.cuss@bms.com';

'richard.lifton@yale.edu'; 'mikael.dolsten@pfizer.com'; (b) (6) Cairns-Smith Sarah; 'dwholley@fnih.org'; Palisch Chase; (b) (6)

Cc: elizabeth.cappello@yale.edu; (b) (6) v; cmelencio@fnih.org; (b) (6)

Subject: TVC Check-in Call

When: Friday, October 25, 2013 8:00 AM-8:30 AM (UTC-05:00) Eastern Time (US &

Canada).

**Where:** ID (b) (6), Phone: (b) (6)

When: Friday, October 25, 2013 8:00 AM-8:30 AM (UTC-05:00) Eastern Time (US &

Canada).

Where: ID: (b) (6), Phone: (b) (6)

Note: The GMT offset above does not reflect daylight saving time adjustments.

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Mobile phone link: (b) (6)

Blackberry quick dial-in: (b) (6) iPhone quick dial-in: (b) (6)

Passcode: (b) (6)

To manually attend the Voice Conference:

- 1. Dial into MeetMe (In-office speed dial: (b) (6)
- 2. Enter the Passcode followed by the # sign

Important commands

- \*0 Operator assistance (also in case of quality issues)
- #0 Conference help menu

Global Access Numbers & Additional commands

(b) (6)<sup>(</sup>

Dial-in Numbers:

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Country Number Argentina +54 1153541176 Australia +61 280318145 Austria +43 1206091303 Bahrain 80004629 Belgium +32 22008540 Brazil +55 11 4700 1524 Brazil (Toll-free) 08000474988 Canada (Toll-free) +18774826140 Chile (Toll-free) 800395032 China +86 4008811648 China (Beijing) +86 10 8527 9944 China (Shanghai) +86 21 2082 3005 Colombia (Toll-free) 018000129898 Croatia (Toll-free) 0800777982 Cyprus (Toll-free) +357 800 924 67 Czech Republic +420 239016131 Denmark +45 43682373 Dominica (Toll-free) +767 1800 988 7777 Dominican Republic (Toll-free) +809 188 849 16 882 Egypt (Toll-free) 08000000268 Finland +358 972519406 France (English Greeting) 0805540269 France (French Greeting) 0805540470 Germany +49 69380789012 Greece +30 210 7260 366 800966116 Hong Kong

+36 17774899

Iceland (Toll-free) 8008867

India (Mumbai) +91 22 6749 7556
India (New Delhi) +91 124 459 7456
Indonesia +62 21 3006 2829
Ireland +353 14073041
Israel (Toll-free) 1809440298
Italy +39 0291483822

Jamaica (Toll-free) 18009883086 Japan +81 332984074 Japan (Toll-free) 0120 995 200

 Japan (Toll-free)
 0120 995 200

 Latvia (Toll-free)
 80004602

 Lithuania (Toll-free)
 880031646

 Luxembourg
 +352 24871300

 Malaysia
 +60 362074380

 Mexico (Mexico City)
 +52 55 3602 5999

 Mexico (Monterrey)
 +52 81 8368 6290

 Mexico (Toll Free)
 01 800 563 0660

 Mexico (Monterrey)
 +52 81 8368 6290

 Mexico (Toll Free)
 01 800 563 0660

 Morocco
 +212 529 02 31 01

 Netherlands
 +31 202035001

 New Zealand
 +64 99123620

 Norway
 +47 22310563

 Peru (Toll-free)
 +51 800 53 710

 Philippings (Singapore Toll)
 +65 66321573

Philippines (Singapore Toll) +65 66221572
Philippines (US Toll) +17203627740
Poland +48 223060169
Portugal +351 217616430
Qatar 00800100003
Romania (Toll-free) 0800 896935

Romania (Toll-free) 0800 896935

Russia +7 499 272 2052

Russia (Toll Free) 8 10 800 240 01 044

Saudi Arabia (Toll free) 900 844 2826

Saudi Arabia (Toll-free) 800 844 2836 Serbia (Toll-free) 0800190074 Singapore +65 66221572 Slovakia +421 268622041 South Africa +27 214273042 +82 234837363 South Korea Spain +34 912757218 Sri Lanka +94 112422182 Sweden +46 851761786 +41 445118498 Switzerland

 Taiwan
 +886 226568438

 Taiwan (Toll free)
 0800 666 503

 Thailand
 +66 2667 3150

 Trinidad and Tobago
 +868 188 820 16 992

 Turkey (Istanbul)
 +902123390199

 Turkey (LandLine only Toll-free)
 00800448823970

Turkey (LandLine only Toll-free) 00800448823970
Ukraine +380 44 495 95 92
Ukraine (Toll-free) 0800502179
United Arab Emirates 80004440049
United Kingdom +44 2030279674
United States +17203627740

United States (Toll-free) +18774826140
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The Boston Consulting Group, Inc.

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# **Target Validation Consortium check-in**

25 October 2013

| (b) | (4), | (b) | (5) |
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| (b) | (4), | (b) | (5) |
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|     |      |     |     |

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 6 Sep 2013 22:14:07 +0000

To: Hudson, Kathy (NIH/OD) [E]

Subject: FW: TVC- schizophrenia

FC

From: Insel, Thomas (NIH/NIMH) [E]
Sent: Friday, September 06, 2013 11:57 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Wholley, David (FNIH) [T]
Subject: TVC- schizophrenia

Francis,

(b) (5)

Tom

(b) (5)

Thomas R. Insel, MD
Director, NIMH/NIH/DHHS
Bethesda, MD 20892

(b) (6) (ph)

From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 26 Sep 2013 02:01:28 +0000

To: Ringel Michael (b) (6);Cairns-Smith Sarah (b) (6)

);Palisch Chase (b) (6)

Cc: Hudson, Kathy (NIH/OD) [E]

Subject: FW: TVC

Steve is right that having these folks listen to the discussion on October 2 would be a good thing. OK?

FC

From: Katz, Stephen I. (NIH/NIAMS) [E]

Sent: Wednesday, September 25, 2013 3:50 PM

To: Collins, Francis (NIH/OD) [E]

Subject: TVC

Hi Francis.....to get NIAID more involved in the RA/Lupus initiative | think that you (or I) should invite Dan Rotrosen (NIAID division director) to the October 2 meeting. I would also like to have Susana Serrata-Sztein (Division director for our Skin and Rheumatic Diseases Program) there since her office will be doing much of the implementing of this effort and putting it on a fast pace. She has been briefed by Bob and me and should hear firsthand the current deliberations and concerns of industry.

Let me know how to proceed.

### Steve

Steve Katz Stephen I. Katz, MD, PHD Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases National Institutes of Health Bldg, 31 Rm, 4C32 Bethesda, MD 20892

NIH... Turning Discovery Into Health

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Tue, 2 Jul 2013 19:54:44 +0000

To: Anderson, James (NIH/OD) [E]; Wilder, Elizabeth (NIH/OD) [E]
Cc: Katz, Stephen I. (NIH/NIAMS) [E]; Carter, Robert (NIH/NIAMS) [E]

Subject: GTEx and synovium

Hi Jim and Betsy,

| Steve Katz may have already asked you this question – | (b) (5) |
|-------------------------------------------------------|---------|
|                                                       |         |
| How could that be explored?                           | 4072    |

Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 22 Aug 2013 14:21:45 +0000

To: Cairns-Smith Sarah (b) (6);Ringel Michael

(b) (6)

Subject: Mads Thomsen

I'm calling Mads in ten minutes.

I see he is also being contacted today at 11:15 AM -- who will be making that call?

**Francis** 

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Wed, 4 Dec 2013 21:29:49 +0000

To: Hudson, Kathy (NIH/OD) [E];Devaney, Stephanie (NIH/OD) [E];Burklow, John

(NIH/OD) [E]

Subject: nomenclature

Possible new name for TVC: Partnership for NextGen Therapeutics

Whaddaya think?

From: Collins, Francis (NIH/OD) [E]
Sent: Fri, 25 Oct 2013 21:45:10 +0000

To: 'mikael.dolsten@pfizer.com';'lundberg\_jan@lilly.com' (lundberg\_jan@lilly.com)

Cc: Cuss, Francis (francis.cuss@bms.com);Cairns-Smith Sarah (b) (6)

);Wholley, David (FNIH) [T];Ringel Michael (b) (6);Hudson,

Kathy (NIH/OD) [E]

Subject: PhRMA and TVC

Hi Mikael and Jan,

Francis Cuss just called me to report on the interactions that you three have been having about the possibility of PhRMA playing some role in the TVC. I understand that there are some reservations about how useful this would be, given the history – but I am not hearing that there are major negatives. From an optics perspective, and perhaps on the chance that the PhRMA SLAC actually turns out to be a useful venue for collaborative ventures, I think it would be appropriate to invite their participation at the dollar figure already proposed. We could then add Bill Chin to the Extended Steering Committee (not the Executive Committee).

Francis Cuss is OK with that plan. But I want to be sure that you two are also. If either of you have objections, please let me know in the next 24 hours or so.

Thanks, Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 21 Jun 2013 16:21:09 +0000

To: Fortune Jennifer

Cc: Ringel Michael; Cairns-Smith Sarah; Bloom (Sartorius) Leah

Subject: Question

Hi Jen,

Just to be sure, (b) (5)

FC

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 3 Oct 2013 02:05:14 +0000

To: Hodes, Richard (NIH/NIA) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: RE: AD TVC

Hi Richard,

Yes, it was an enjoyable respite! And the outcome seemed to be just what we hoped for

(b) (5)

I know that Kathy has been talking with FDA, I will let the two of you figure out the timing once the shutdown is over, but I agree it would be good to have FDA engaged in the new version of the white paper.

FC

From: Hodes, Richard (NIH/NIA) [E]

Sent: Wednesday, October 02, 2013 1:19 PM

To: Hudson, Kathy (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]

Subject: RE: AD TVC

This morning's TVC meeting was a most enjoyable respite from the interruption in research progress. Given comments, may we go ahead with FDA contact on the AD initiative once the federal government is back in business?

Thanks

From: Hodes, Richard (NIH/NIA) [E]

Sent: Thursday, September 26, 2013 5:30 PM

**To:** Hudson, Kathy (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]

Subject: RE: AD TVC

(b) (5)

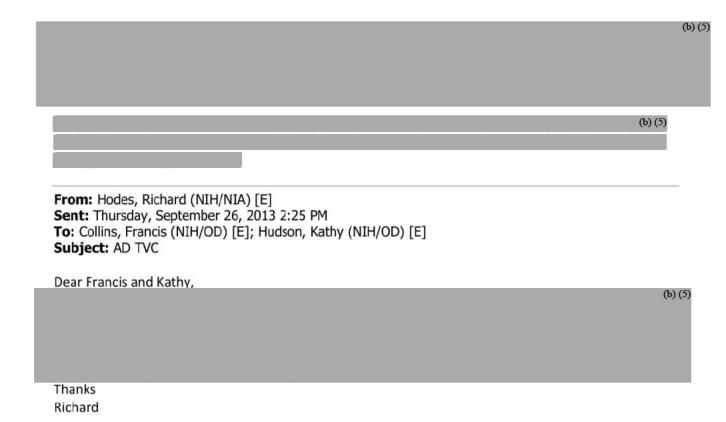
From: Hudson, Kathy (NIH/OD) [E]

Sent: Thursday, September 26, 2013 3:43 PM

To: Hodes, Richard (NIH/NIA) [E]; Collins, Francis (NIH/OD) [E]

Subject: RE: AD TVC

Yes! The plan was to include stakeholders and fda folks. I think David Wholley has given this some thought as well so perhaps we should confer before we extend invites.



From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 5 Dec 2013 20:56:05 +0000

To: Palisch Chase;Ringel Michael;Hodes, Richard (NIH/NIA) [E];Rodgers,

Griffin (NIH/NIDDK) [E]; 'lundberg\_jan@lilly.com'; Insel, Thomas (NIH/NIMH) [E]; Katz,

Stephen I. (NIH/NIAMS) [E];'francis.cuss@bms.com';'richard.lifton@yale.edu';Hudson, Kathy

(NIH/OD) [E]; Wholley, David (FNIH) [T]; Cairns-Smith

Sarah; 'mikael.dolsten@pfizer.com'; Carter, Robert (NIH/NIAMS) [E]

Cc: McManus, Ayanna (NIH/OD) [E];Bronson, Charlette (NIH/NIA)

[E];Melencio, Cheryl (FNIH) [T];edmonds\_pamela\_j@lilly.com;Wilkerson, Anita D. (NIH/NIDDK) [E];debra.zander@bms.com;Poole, Charlene (NIH/NIDDK) [E];Holt, Tracy

(NIH/NIMH) [E]; Meltzer, Sherry (NIH/NIAMS) [E]; Schulke, Hilda (NIH/OD)

[E];elizabeth.cappello@yale.edu;Brawley, David (NIH/NIDDK)

[E];tim.wagner@pfizer.com;Wood, Gretchen (NIH/OD) [E]

Subject: RE: Bi-weekly TVC Check-in Call

All NIH/FNIH folks are welcome to join the TVC call in Conference Room

(b) (6)

). If you are available at 8 AM tomorrow, please join us.

Thanks, Francis

From: Palisch Chase [mailto

(b) (6)

Sent: Thursday, December 05, 2013 2:43 PM

**To:** Ringel Michael; Hodes, Richard (NIH/NIA) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; 'lundberg\_jan@lilly.com'; Insel, Thomas (NIH/NIMH) [E]; Katz, Stephen I. (NIH/NIAMS) [E]; 'francis.cuss@bms.com'; Collins, Francis (NIH/OD) [E]; 'richard.lifton@yale.edu'; Hudson, Kathy (NIH/OD) [E]; Wholley, David (FNIH) [T]; Cairns-Smith Sarah;

'mikael.dolsten@pfizer.com'; Carter, Robert (NIH/NIAMS) [E]

Cc: McManus, Ayanna (NIH/OD) [E]; Bronson, Charlette (NIH/NIA) [E]; Melencio, Cheryl (FNIH) [T]; edmonds\_pamela\_j@lilly.com; Wilkerson, Anita D. (NIH/NIDDK) [E]; debra.zander@bms.com; Poole, Charlene (NIH/NIDDK) [E]; Holt, Tracy (NIH/NIMH) [E]; Meltzer, Sherry (NIH/NIAMS) [E]; Schulke, Hilda (NIH/OD) [E]; elizabeth.cappello@yale.edu; Brawley, David (NIH/NIDDK) [E]; tim.wagner@pfizer.com; Wood, Gretchen (NIH/OD) [E]

Subject: RE: Bi-weekly TVC Check-in Call

Hello everyone,

Attached are the materials for tomorrow's TVC check-in. During the meeting, we will discuss the recent progress from each Steering Committee's face-to-face meetings.

Please let me know if you have any questions in advance of the meeting.

Best,

Chase

Chase Palisch
THE BOSTON CONSULTING GROUP
Tel. (b) (6) Mobile +1 (b) (6)

----Original Appointment----

From: Ringel Michael

Sent: Tuesday, October 29, 2013 5:15 PM

| 10:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (6) (6); 'lundberg_jan@ilily.com';                                                                   |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | (b) (6); 'francis.cuss@bms.com';                                                                     |
| (b) (6); 'richard.lifton@y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                      |
| (b) (6) '                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | airns-Smith Sarah; 'mikael.dolsten@pfizer.com'                                                       |
| Cc:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (6); cmelencio@fnih.org;                                                                         |
| edmonds_pamela_j@lilly.com;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | (b) (6): debra.zander@bms.com;                                                                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>(b) (6)</b> :                                                                                     |
| elizabeth.cappello                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | (b) (6)                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | (b) (6)                                                                                              |
| Subject: Bi-weekly TVC Check-in Cal                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                      |
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| & Canada).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                      |
| <b>Where:</b> ID: (b) (6), Phone: (                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                      |
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| When: Occurs every 2 weeks on Frida                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | ay effective 11/8/2013 until 1/10/2014 from                                                          |
| 8:00 AM to 8:30 AM (UTC-05:00) East                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 57.0                                                                                                 |
| Where: ID: (b) (6), Phone: +                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (b) (6)                                                                                              |
| where ib.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                      |
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Germany +49 69380789012
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Hong Kong (Toll-free) 800966116
Hungary +36 17774899

lceland (Toll-free) +36 1777 8008867

India (Mumbai) +91 22 6749 7556
India (New Delhi) +91 124 459 7456
Indonesia +62 21 3006 2829
Ireland +353 14073041
Israel (Toll-free) 1809440298
Italy +39 0291483822
Jamaica (Toll-free) 18009883086

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 Japan
 +81 332984074

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 0120 995 200

 Latvia (Toll-free)
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 Lithuania (Toll-free)
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 Luxembourg
 +352 24871300

 Malaysia
 +60 362074380

 Mexico (Mexico City)
 +52 55 3602 5999

 Mexico (Monterrey)
 +52 81 8368 6290

 Mexico (Toll Free)
 01 800 563 0660

 Marrages
 +313 530 03 31 01

 Mexico (Toll Free)
 01 800 563 0660

 Morocco
 +212 529 02 31 01

 Netherlands
 +31 202035001

 New Zealand
 +64 99123620

 Norway
 +47 22310563

 Peru (Toll-free)
 +51 800 53 710

 Philippines (Singapore Toll)
 +65 66221572

Philippines (Singapore Toll) +05 66221572
Philippines (US Toll) +17203627740
Poland +48 223060169
Portugal +351 217616430
Qatar (Toll-free) 00800100003
Romania (Toll-free) 0800 896935
Russia +7 499 272 2052

Russia (Toll Free) 8 10 800 240 01 044 Saudi Arabia (Toll-free) 800 844 2836 Serbia (Toll-free) 0800190074 Singapore +65 66221572 Slovakia +421 268622041 South Africa +27 214273042 South Korea +82 234837363 +34 912757218 Spain Sri Lanka +94 112422182

 Sweden
 +46 851761786

 Switzerland
 +41 445118498

 Taiwan
 +886 226568438

 Taiwan (Toll free)
 0800 666 503

 Thailand
 +66 2667 3150

Trinidad and Tobago +868 188 820 16 992

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Turkey (LandLine only Toll-free)
Ukraine
Ukraine (Toll-free)
United Arab Emirates (Toll-free)
United Kingdom
United States
United States (Toll-free)
Venezuela (Toll-free)

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Vietnam (Toll-free)

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From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 5 Dec 2013 17:40:27 +0000

To: Ringel Michael Subject: RE: Calico

Done!

From: Ringel Michael [mailto (b) (6)

Sent: Wednesday, December 04, 2013 11:49 AM

To: Collins, Francis (NIH/OD) [E]

Subject: Calico

Francis,

Thanks for offering to help make the connection to Art. Below is an email that you could forward, with resume attached.

Warm regards, Michael

-----

Dear Dr. Levinson,

(b) (6)

My current work is focused on supporting biopharma R&D organizations. I can provide several references on my capabilities in both science and business as desired; two in biopharma that have offered so far are Mikael Dolsten (President R&D, Pfizer), and Francis Cuss (EVP R&D, BMS), whom I have supported in revitalizing their R&D organizations, and two academics are David Altshuler (Chief Academic Officer, Broad Institute) and Ned Wingreen (Acting Director, Lewis-Sigler Institute).

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I am currently leading BCG's support of several projects on the application of big data to disentangle currently confounded diseases and pathways. One with Francis Collins at NIH that will be announced early next year (hence, why I've asked him to forward this note to you), one with the Director of Lawrence Livermore National Laboratory, and one private effort involving a biopharma and a big data company. Again, I can provide references as desired.

(b) (6)

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|                                 |                 | (b) (6) |
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| Kind regards,<br>Michael Ringel |                 |         |
| Michael Ringel                  | (b) (6) (b) (6) |         |
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From: Collins, Francis (NIH/OD) [E]
Sent: Mon, 2 Dec 2013 01:25:55 +0000

To: Ringel Michael Subject: RE: Calico

Got it. Yes, please send the resume, because I suspect that's the first thing Art will ask about.

FC

From: Ringel Michael [mailto (b) (6)

Sent: Sunday, December 01, 2013 7:30 PM

To: Collins, Francis (NIH/OD) [E]

Subject: Re: Calico

Francis,

(b) (6)

Any help you can give, either introduction or serving as a reference based on our work on TVC together, would be much appreciated.

I am happy to provide a resume- in brief, valedictorian at high school ranked #1 public school in US, #1 in biology department at Princeton undergrad, PhD at Imperial College (NSF and Fulbright fellowships), law degree from Harvard, successful career as Partner at BCG. A few hard knocks along the way as well.

Kind regards, Michael

From: Collins, Francis (NIH/OD) [E] [mailto: (b) (6)
Sent: Sunday, December 01, 2013 05:41 PM Central Standard Time

To: Ringel Michael Subject: RE: Calico

Hi Michael,

I know Art a bit, but not particularly well. I might be able to help, but I'd need to know about your intentions.

FC

From: Ringel Michael [mailto (b) (6)

Sent: Sunday, December 01, 2013 5:22 PM

To: Collins, Francis (NIH/OD) [E]

Subject: Calico

## Francis,

I hope you are doing well and had a nice Thanksgiving break. I'm actually reaching out on a personal favor.

I am interested in getting in touch with Art Levinson at Calico. Are you connected with him and if so, would you be willing to make an introduction?

Kind regards, Michael

Michael Ringel, Ph.D.
Partner and Managing Director

THE BOSTON CONSULTING GROUP
Exchange Place, 31st floor
Boston, Massachusetts 02109 \* United States

Tel. (b) (6) \* Mobile + (b) (6)

Assistant: Lindsey Mastroianni
Tel. (b) (6) (b) (6)

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 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Sun, 1 Dec 2013 23:41:37 +0000

To: Ringel Michael Subject: RE: Calico

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From: Ringel Michael [mailto (b) (6)

Sent: Sunday, December 01, 2013 5:22 PM

To: Collins, Francis (NIH/OD) [E]

Subject: Calico

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Michael Ringel, Ph.D.
Partner and Managing Director

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Tel. (b) (6) • Mobile + (b) (6) (b) (6)

Assistant: Lindsey Mastroianni

Tel. (b) (6) (b) (6)

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otherwise authorized to receive this message, you should not use, copy, disclose or take any action based on this email or any information contained in the message. If you have received this material in error, please advise the sender immediately by reply e-mail and delete this message. Thank you.

From: Collins, Francis (NIH/OD) [E] Sent: Thu, 5 Dec 2013 18:22:32 +0000 To: Ringel Michael Subject: RE: Calico And Art has already acknowledged receiving my message, so I know it got through. FC From: Ringel Michael [mailto] (b) (6) Sent: Thursday, December 05, 2013 12:53 PM To: Collins, Francis (NIH/OD) [E] Subject: RE: Calico Thank you! Michael Ringel, Ph.D. Partner and Managing Director THE BOSTON CONSULTING GROUP Tel (b) (6) Mobile +1 From: Collins, Francis (NIH/OD) [E] [mailto] (b)(6)Sent: Thursday, December 05, 2013 12:40 PM To: Ringel Michael Subject: RE: Calico Done! From: Ringel Michael [mailto] (b)(6)Sent: Wednesday, December 04, 2013 11:49 AM To: Collins, Francis (NIH/OD) [E] Subject: Calico Francis, Thanks for offering to help make the connection to Art. Below is an email that you could forward, with resume attached. Warm regards, Michael

Dear Dr. Levinson,

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| Kind regards,                  |         |         |         |
| Kind regards,<br>Michael Ringe | (b) (6) | (b) (6) |         |
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From: Collins, Francis (NIH/OD) [E]
Sent: Sun, 21 Jul 2013 13:47:04 +0000

To: Cuss, Francis

Cc: Wood, Gretchen (NIH/OD) [E]

Subject: RE: CEO outreach

Dear Francis,

Thanks for your thoughtful and illuminating note - very helpful, and no apology necessary!

(b) (4) this month, to see

if there is an effective way to pursue that conversation.

And yes, I'd like to know more about your priority-setting process. I'll ask Gretchen (cc'd) here to look for a time where we could chat on the phone.

Regards, Francis

From: Cuss, Francis [mailto:francis.cuss@bms.com]

Sent: Friday, July 19, 2013 2:24 PM To: Collins, Francis (NIH/OD) [E]

Subject: CEO outreach

Dear Francis,

I just wanted to apologize if my response to your generous offer to meet Pharma CEOs to show your support for TVC sounded dissonant during our call today. On reflection I appreciate that in the short term you were looking to help ensure success by getting broad backing from Pharma for the TVC; while I was considering the next stage and the value of emphasizing the learnings from (what I hope will be) a successful TVC for a potential new model in precompetitive activities. For my part, I know that my CEO expects R&D to make decisions on where invest BMS's resources based on the company's priorities and your advocacy would probably not make much difference at this stage, but of course I can't speak for the CEO/CSO relationship in other companies.

(b) (4)

In short, my judgment is that your advocacy would be even more effective in explaining the important and unique elements of this process as a model for the future rather than solely near term fund-raising, although that does presuppose the outreach goes well.

On a separate topic, which I also touched on today, I would be happy to share with you how we make priorities around disease areas, individual projects and alight on budgets, if that would help you understand the biopharma psyche in this regard. Also I can explain why a large proportion of our budget is not really discretionary. Of course I don't know how comparable BMS is to other companies, but our experience may be enlightening for you.

Best, Francis

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| To:                                      | Palisch Chase                                                                                                          |         |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------|---------|
| Cc:<br>Subject:                          | Ringel Michael; Cairns-Smith Sarah; Hudson, Kathy (NIH/OD) [E] RE: Consortium naming                                   |         |
| Jan, 200.                                | ne. consortium natuung                                                                                                 |         |
| Hi Chase,                                |                                                                                                                        |         |
| Yes, I think conside developing a strate | eration for a new name would be worthwhile. Please work with Kathy Hudson on egy.                                      |         |
| Best, Francis                            |                                                                                                                        |         |
| To: Collins, Francis                     | October 02, 2013 10:44 PM<br>s (NIH/OD) [E]<br>; Cairns-Smith Sarah                                                    | _       |
| Hi Francis,                              |                                                                                                                        |         |
|                                          | f your help and leadership for today's presentation. It went very well, and we've tive feedback from industry members. |         |
|                                          |                                                                                                                        | (b) (4) |
|                                          |                                                                                                                        |         |
|                                          |                                                                                                                        |         |
|                                          |                                                                                                                        |         |
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|                                          |                                                                                                                        |         |
|                                          |                                                                                                                        |         |
|                                          |                                                                                                                        |         |
|                                          |                                                                                                                        |         |
| We look forward to                       | o hearing your thoughts. Please let us know if you have any questions.                                                 |         |
| Best,                                    |                                                                                                                        |         |
| Chase and the BCG                        | 6 team                                                                                                                 |         |
|                                          |                                                                                                                        |         |
| Chase Palisch                            |                                                                                                                        |         |
| THE BOSTON CONSU                         | ILTING GROUP                                                                                                           |         |

Collins, Francis (NIH/OD) [E]

Thu, 3 Oct 2013 03:09:35 +0000

From:

Sent:

| 4800 Ham  | pden Lane | e, Suite | 400                        |        |
|-----------|-----------|----------|----------------------------|--------|
| Bethesda, | Maryland  | 20814    | <ul> <li>United</li> </ul> | States |

| Tel. | <b>(b) (6)</b> • Mobile +1 | (b) (6) |  |
|------|----------------------------|---------|--|
|      | (b) (6)                    |         |  |
|      |                            |         |  |

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|   | From:<br>Sent:<br>To:<br>Subject:                                           | Collins, Francis (NIH/OD) [E] Fri, 7 Jun 2013 21:24:38 +0000 Lifton, Richard RE: Follow up on Rodgers |         |
|---|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|---------|
|   | Hi Rick, Thanks for your note –                                             | I'm glad you are checking back in on TVC, we have missed you!                                         |         |
|   | Thanks for your note                                                        | Thi glad you are elecking back in on Tve, we have inissed you.                                        | (b) (   |
| i |                                                                             |                                                                                                       | (b) (   |
|   | Best, Francis                                                               | H/OD) [E]                                                                                             |         |
|   |                                                                             |                                                                                                       | (b) (4) |
|   | I will of course keep you<br>Best wishes-<br>Rick                           | ur response confidential.                                                                             |         |
|   | (NIH/OD) [E]; Cairns-Sr<br>'lundberg_jan@lilly.com<br>edmonds_pamela_j@lill |                                                                                                       |         |

Fortune Jennifer; Chand Nikhilesh; Wagner, Tim; Insel, Thomas (NIH/NIMH) [E]; Hodes, Richard (NIH/NIA) [E]; Holt, Tracy (NIH/NIMH) [E]; Sara Ponzo; 'garry@appletreepartners.com'; Meltzer, Sherry (NIH/NIAMS) [E]

Subject: Follow up on Rodgers

Something I meant to mention in the call just now: with your support, I have extended an offer to Griff Rodgers (Director, NIDDK) to join the Steering Committee, and he has accepted. He was not able to join the call this morning, but will participate in the discussion of the white paper on T2D next Thursday. Going forward, the SC e-mail list should include Griff and his assistant.

Francis

| To:<br>Cc:<br>Subject:                                 | Palisch Chase Ringel Michael; Cairns-Smith Sarah RE: Initial TVC commitment status                                                                   |         |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| Hi all,                                                |                                                                                                                                                      |         |
|                                                        |                                                                                                                                                      | (b) (4  |
|                                                        |                                                                                                                                                      |         |
|                                                        |                                                                                                                                                      |         |
|                                                        |                                                                                                                                                      |         |
|                                                        |                                                                                                                                                      |         |
| Francis                                                |                                                                                                                                                      |         |
| To: Collins, Fran<br>Cc: Ringel Mich<br>Subject: FW: I | Chase [mailto 6) (6)  July 16, 2013 4:04 PM  ncis (NIH/OD) [E]  ael; Cairns-Smith Sarah  initial TVC commitment status                               |         |
| Dear Francis,                                          |                                                                                                                                                      | (b) (4) |
|                                                        |                                                                                                                                                      |         |
|                                                        |                                                                                                                                                      | (b) (4) |
|                                                        |                                                                                                                                                      |         |
|                                                        | VC solicitation will continue to be an iterative process, and we look f<br>and feedback during this week's check-in. Please let me know if you<br>e. |         |
| Thanks,                                                |                                                                                                                                                      |         |
| Chase                                                  |                                                                                                                                                      |         |
| Chase Palisch THE BOSTON CON Tel. + (b) (6             | NSULTING GROUP  6) • Mobile +1 (b) (6)                                                                                                               |         |

Collins, Francis (NIH/OD) [E]

Wed, 17 Jul 2013 00:37:44 +0000

From:

Sent:

From: Cuss, Francis [mailto:francis.cuss@bms.com]

Sent: Tuesday, July 16, 2013 2:54 PM

To: Palisch Chase

**Cc:** Ringel Michael; Cairns-Smith Sarah **Subject:** RE: Initial TVC commitment status

Dear Chase, (b) (4) Best,

From: Palisch Chase [mailto (b) (6)

Sent: Wednesday, July 10, 2013 12:40 PM

To: Cuss, Francis

Francis

**Cc:** ringel.michaelbcg.com; Cairns-Smith Sarah **Subject:** Initial TVC commitment status

Dear Francis,

In our original outreach plan we proposed that each Core Steering Committee member indicate their initial support for consortium proposals by this Friday, July 12th. In advance the Core SC check-in, we just wanted to check on the status of your commitment.

Could you please let us know by tomorrow morning if you will still be able to make an initial pledge this Friday?

We look forward to your reply.

Thanks, Chase and the BCG team

Chase Palisch

THE BOSTON CONSULTING GROUP

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 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Wed, 31 Jul 2013 10:45:57 +0000

To: richard.lifton@yale.edu

Cc: Ringel Michael (b) (6); Katz, Stephen I. (NIH/NIAMS)

[E];Carter, Robert (NIH/NIAMS) [E]

Subject: RE: Inquiry on TVC

Hi Rick,

I'm glad to hear of the interest from Mark Curran

(b) (4) I passed along the questions that he is posing

(b) (4)

and/or looking at the complete white paper.

I'm also ccing Michael Ringel of BCG, who knows Mark well, and might be another useful contact about TVC. Michael would be glad to call Mark as well.

Best, Francis

From: Carter, Robert (NIH/NIAMS) [E] Sent: Tuesday, July 30, 2013 5:37 PM To: Collins, Francis (NIH/OD) [E]

Cc: Ringel Michael (b) (6); Katz, Stephen I. (NIH/NIAMS) [E]

Subject: RE: Inquiry on TVC

Francis



|                                                                                                                                                       | (b) (      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
|                                                                                                                                                       |            |
|                                                                                                                                                       |            |
|                                                                                                                                                       |            |
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|                                                                                                                                                       |            |
|                                                                                                                                                       |            |
|                                                                                                                                                       |            |
|                                                                                                                                                       |            |
| Would be delighted to clarify or provide further info. One option might be to provide partner express potential interest with the full proposal.      | s who      |
| Cheers,                                                                                                                                               |            |
| Bob                                                                                                                                                   |            |
| Sent: Tuesday, July 30, 2013 3:14 PM  To: Carter, Robert (NIH/NIAMS) [E]  Cc: Ringel Michael (b) (6)  Subject: FW: Inquiry on TVC                     |            |
| Hi Bob,                                                                                                                                               |            |
| See note below from Rick Lifton, (b) (4                                                                                                               | ). Can you |
| suggest responses for me to share with Rick?                                                                                                          |            |
| Thanks, Francis                                                                                                                                       |            |
| From: Lifton, Richard [mailto:richard.lifton@yale.edu] Sent: Tuesday, July 30, 2013 8:51 AM To: Collins, Francis (NIH/OD) [E] Subject: Inquiry on TVC |            |
| Dear Francis,                                                                                                                                         |            |
| I received the inquiry below from Mark Curran,                                                                                                        | 9) (4)     |
|                                                                                                                                                       |            |
| D                                                                                                                                                     |            |

Best-

| Rick                                                                                                            |         |         |
|-----------------------------------------------------------------------------------------------------------------|---------|---------|
| Rick, Hope you are well.                                                                                        | (b) (4) |         |
| I'm positive on the RA / SLE projects with two caveats:                                                         |         |         |
| The positive of the fully SEE projects with two cuvetis.                                                        |         | (b) (4) |
|                                                                                                                 |         |         |
|                                                                                                                 |         |         |
|                                                                                                                 |         |         |
| If email doesn't work we can talk this week. I'll peel myself out of whatever meeting I'm have this discussion. | in to   |         |
| Thanks,                                                                                                         |         |         |
| Mark                                                                                                            |         |         |
| Mark E. Curran, Ph.D. Vice President, Immunology Systems Pharmacology & Biomarkers                              |         |         |
| Janssen Research & Development                                                                                  |         |         |

Immunology Therapeutic Area

1400 McKean Road Springhouse, PA 19477 Tel: 215.793.7559 Mobile: (b) (6) Mcurran3@its.jnj.com From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 22 Aug 2013 15:00:29 +0000
To: Cairns-Smith Sarah;Ringel Michael

Cc: Palisch Chase
Subject: RE: Mads Thomsen

No problem. One of our spreadsheets said today – but Mads knew it had been rescheduled.

I'll send a summary later today or this evening on my calls with Mads, Jim Sullivan, and Norbert Bischofberger.

Calls to John Reed and Doug Williams are coming up soon.

FC

From: Cairns-Smith Sarah [mailto (b) (6)

**Sent:** Thursday, August 22, 2013 10:57 AM **To:** Collins, Francis (NIH/OD) [E]; Ringel Michael

Cc: Palisch Chase

Subject: RE: Mads Thomsen

Sorry – just got this – the meeting has been rescheduled to September – was between Mikael and Mads.

Did Mads think it was today?

Sarah

Sarah Cairns-Smith
Partner and Managing Director
THE BOSTON CONSULTING GROUP
Tel. (b) (6) - Mobile (b) (6)

From: Collins, Francis (NIH/OD) [E] [mailto (b) (6)

**Sent:** Thursday, August 22, 2013 10:22 AM **To:** Cairns-Smith Sarah; Ringel Michael

Subject: Mads Thomsen

I'm calling Mads in ten minutes.

I see he is also being contacted today at 11:15 AM -- who will be making that call?

Francis

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 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Wed, 5 Jun 2013 22:05:26 +0000

To: Dolsten, Mikael

Cc: RINGEM01; Wood, Gretchen (NIH/OD) [E]

Subject: RE: Message

## Excellent!

----Original Message----

From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Wednesday, June 05, 2013 5:58 PM To: Collins, Francis (NIH/OD) [E]

Cc: RINGEM01 Subject: Message

My meetings on the Hill now ends 1145 am (one senator meeting got canceled) and I should now be in time at NIH for start of TVC 1 pm Look forward to see you

Sent from my iPhone

From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 25 Jul 2013 11:09:58 +0000

To: David Altshuler
Cc: Robert Plenge

Subject: RE: NRDD on target validation

## Terrific article!

From: David Altshuler [mailto:ALTSHULER@MOLBIO.MGH.HARVARD.EDU]

Sent: Wednesday, July 24, 2013 10:23 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Robert Plenge

Subject: NRDD on target validation

**FYI** 

Best,

David

David Altshuler MD, PhD

Deputy Director and Chief Academic Officer | Broad Institute of Harvard and MIT Professor of Genetics and of Medicine | Harvard Medical School and Massachusetts General Hospital Adjunct Professor of Biology | Massachusetts Institute of Technology 7 Cambridge Center | Cambridge, MA 02142 | 617 726-5940

From: Collins, Francis (NIH/OD) [E]
Sent: Tue, 29 Oct 2013 20:31:01 +0000

To: Wholley, David (FNIH) [T]

Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6)
1; Palisch Chase (b) (6); Hudson, Kathy (NIH/OD) [E]

Subject: RE: PhRMA and TVC

Hmm. When I spoke by phone with

(b) (4) (b) (4)

But I hope this doesn't create a major embarrassment, or come across as a bait and switch – if you think it might, we could probably reconsider.

FC

From: Wholley, David (FNIH) [T]

Sent: Tuesday, October 29, 2013 4:19 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Ringel Michael (b) (6) Cairns-Smith Sarah (b) (6); Palisch

Chase (b) (6); Hudson, Kathy (NIH/OD) [E]

Subject: RE: PhRMA and TVC

(b)(4)

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, October 29, 2013 3:54 PM

To: Wholley, David (FNIH) [T]

Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6) Palisch

Chase (b) (6) Hudson, Kathy (NIH/OD) [E]

Subject: RE: PhRMA and TVC

Great. But let's be clear, (b) (5)

FC

From: Wholley, David (FNIH) [T]

Sent: Tuesday, October 29, 2013 3:50 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6); Palisch

Chase (b) (6); Hudson, Kathy (NIH/OD) [E]

Subject: RE: PhRMA and TVC

No, Francis, I have already taken care of it (b)(5)(b)(5)David From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, October 29, 2013 3:47 PM To: Wholley, David (FNIH) [T] Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6); Palisch (b) (6); Hudson, Kathy (NIH/OD) [E] Chase Subject: FW: PhRMA and TVC Hi David, I just realized I wasn't certain how the loop was to be closed with (b)(5)FC ----Original Message----From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com] Sent: Friday, October 25, 2013 5:51 PM To: Collins, Francis (NIH/OD) [E] Cc: 'lundberg\_jan@lilly.com' (lundberg\_jan@lilly.com); Cuss, Francis (francis.cuss@bms.com); Cairns-(b) (6) Wholley, David (FNIH) [T]; RINGEM01; Hudson, Kathy Smith Sarah (NIH/OD) [E] Subject: Re: PhRMA and TVC I am fine Mikael From: Jan Lundberg [mailto:lundberg\_jan@lilly.com] Sent: Saturday, October 26, 2013 6:38 AM To: Collins, Francis (NIH/OD) [E] Subject: Re: PhRMA and TVC Ok with me Best Jan Skickat från min iPhone Oct 25, 2013 kl. 4:45 PM skrev "Collins, Francis (NIH/OD) [E]" (b)(6)

Hi Mikael and Jan,

Francis Cuss just called me to report on the interactions that you three have been having about the possibility of PhRMA playing some role in the TVC. I understand that there are some reservations about how useful this would be, given the history – but I am not hearing that there are major negatives. From an optics perspective, and perhaps on the chance that the PhRMA SLAC actually turns out to be a useful venue for collaborative ventures, I think it would be appropriate to invite their participation at the dollar figure already proposed. We could then add Bill Chin to the Extended Steering Committee (not the Executive Committee).

Francis Cuss is OK with that plan. But I want to be sure that you two are also. If either of you have objections, please let me know in the next 24 hours or so.

Thanks, Francis

Collins, Francis (NIH/OD) [E] From: Tue, 29 Oct 2013 19:54:27 +0000 Sent: To: Wholley, David (FNIH) [T] Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6) ;Palisch Chase (b) (6) Hudson, Kathy (NIH/OD) [E] RE: PhRMA and TVC Subject: (b) (5) Great. But let's be clear, FC From: Wholley, David (FNIH) [T] Sent: Tuesday, October 29, 2013 3:50 PM To: Collins, Francis (NIH/OD) [E] Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6) Palisch Chase (b) (6) Hudson, Kathy (NIH/OD) [E] Subject: RE: PhRMA and TVC No, Francis, I have already taken care of it (b)(5)(b)(5)David From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, October 29, 2013 3:47 PM To: Wholley, David (FNIH) [T] Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6); Palisch Chase (b) (6); Hudson, Kathy (NIH/OD) [E] Subject: FW: PhRMA and TVC Hi David, I just realized I wasn't certain how the loop was to be closed (b) (5) FC ----Original Message----From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com] Sent: Friday, October 25, 2013 5:51 PM To: Collins, Francis (NIH/OD) [E] Cc: 'lundberg\_jan@lilly.com' (lundberg\_jan@lilly.com); Cuss, Francis (francis.cuss@bms.com); Cairns-(b) (6); Wholley, David (FNIH) [T]; RINGEM01; Hudson, Kathy Smith Sarah (NIH/OD) [E]

Subject: Re: PhRMA and TVC

I am fine Mikael

From: Jan Lundberg [mailto:lundberg\_jan@lilly.com]

Sent: Saturday, October 26, 2013 6:38 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: PhRMA and TVC

Ok with me

Best Jan

Skickat från min iPhone

Oct 25, 2013 kl. 4:45 PM skrev "Collins, Francis (NIH/OD) [E]" (b) (6)

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Collins, Francis (NIH/OD) [E] From: Sent: Wed, 30 Oct 2013 00:25:33 +0000 To: Wholley, David (FNIH) [T] Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6) ;Palisch Chase (b) (6); Hudson, Kathy (NIH/OD) [E] RE: PhRMA and TVC Subject: Ok but please make the case (b) (5) From: Wholley, David (FNIH) [T] Sent: Tuesday, October 29, 2013 5:15 PM To: Collins, Francis (NIH/OD) [E] Cc: Ringel Michael (b) (6) Cairns-Smith Sarah (b) (6); Palisch (b) (6); Hudson, Kathy (NIH/OD) [E] Chase Subject: RE: PhRMA and TVC Why don't I just ask him? It may be that (b)(5)From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, October 29, 2013 4:31 PM To: Wholley, David (FNIH) [T] Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6) Palisch Chase (b) (6); Hudson, Kathy (NIH/OD) [E] Subject: RE: PhRMA and TVC Hmm. (b)(5)But I hope this doesn't create a major embarrassment, or come across as a bait and switch - if you think it might, we could probably reconsider. FC From: Wholley, David (FNIH) [T] Sent: Tuesday, October 29, 2013 4:19 PM To: Collins, Francis (NIH/OD) [E] Cc: Ringel Michael (b) (6) Cairns-Smith Sarah (b) (6) Palisch Chase (b) (6); Hudson, Kathy (NIH/OD) [E] Subject: RE: PhRMA and TVC (b)(5)Francis, I recall when we discussed this last Friday that (b) (5)

(b)(5)From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, October 29, 2013 3:54 PM To: Wholley, David (FNIH) [T] Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6) Palisch (b) (6); Hudson, Kathy (NIH/OD) [E] Chase Subject: RE: PhRMA and TVC (b) (5) Great. But let's be clear, FC From: Wholley, David (FNIH) [T] Sent: Tuesday, October 29, 2013 3:50 PM To: Collins, Francis (NIH/OD) [E] Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6); Palisch Chase (b) (6) Hudson, Kathy (NIH/OD) [E] Subject: RE: PhRMA and TVC (b)(5)No, Francis, I have already taken care of it (b) (5) David From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, October 29, 2013 3:47 PM To: Wholley, David (FNIH) [T] Cc: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6); Palisch (b) (6) Hudson, Kathy (NIH/OD) [E] Chase Subject: FW: PhRMA and TVC Hi David, I just realized I wasn't certain how the loop was to be closed (b)(5)FC ----Original Message----From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com] Sent: Friday, October 25, 2013 5:51 PM To: Collins, Francis (NIH/OD) [E] Cc: 'lundberg\_jan@lilly.com' (lundberg\_jan@lilly.com); Cuss, Francis (francis.cuss@bms.com); Cairns-(b) (6) Wholley, David (FNIH) [T]; RINGEM01; Hudson, Kathy Smith Sarah (NIH/OD) [E] Subject: Re: PhRMA and TVC

I am fine Mikael

From: Jan Lundberg [mailto:lundberg\_jan@lilly.com]

Sent: Saturday, October 26, 2013 6:38 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: PhRMA and TVC

Ok with me

Best Jan

Skickat från min iPhone

Oct 25, 2013 kl. 4:45 PM skrev "Collins, Francis (NIH/OD) [E]" (b) (6

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Francis Cuss is OK with that plan. But I want to be sure that you two are also. If either of you have objections, please let me know in the next 24 hours or so.

Thanks, Francis

Collins, Francis (NIH/OD) [E] From: Sent: Mon, 5 Aug 2013 19:23:38 +0000 To: Wholley, David (FNIH) [T] Subject: RE: PhRMA discussion Hi David, Thanks for your note -(b) (5) We had a very friendly call, and he outlined many of the same points in your message. He outlined the same list of priorities for the SLAC, and thought TVC might actually fit into the fourth one too, given the potential for White House interest in the consortium model. He sounded very supportive of the project – asked questions about how we would co-fund, was glad to hear you were involved. Apparently you and Maria are going down to see him shortly, feel free to bring this up. I am sending him the "pitch deck". (b)(5)Thanks, Francis From: Wholley, David (FNIH) [T] Sent: Monday, August 05, 2013 2:16 PM To: Collins, Francis (NIH/OD) [E] Subject: PhRMA discussion



**David Wholley** 

Director, The Biomarkers Consortium

Foundation for the National Institutes of Health

9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org

Direct (301) 594-6343 | Fax (301) 480-2752

Combined Federal Campaign (CFC) #29165

Recipient of 4-star rating from Charity Navigator, 2007-2011



From: Collins, Francis (NIH/OD) [E]

Sent: Mon, 19 Aug 2013 20:37:03 +0000

To: 'nbischofberger@gilead.com'

Cc: 'Traci.Carrithers@gilead.com';McManus, Ayanna (NIH/OD) [E];Wood, Gretchen

(NIH/OD) [E];Ringel Michael (b) (6);Cairns-Smith Sarah (b) (6)

Subject: RE: Target Validation Call

Attachments: TVC - Overview Discussion - 130715 - vFinal.pptx

Hi Norbert,

It was a pleasure to speak with you earlier today. Attached is a ppt file that provides details of the current Target Validation Consortium plan. I would be glad to answer further questions about this, as would my industry colleagues Dolsten, Lundberg, or Cuss. It would be great to have Gilead as a participant in one or more of these projects.

Best regards, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, August 16, 2013 4:39 PM
To: 'nbischofberger@qilead.com'

Cc: 'Traci.Carrithers@gilead.com'; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

Subject: Target Validation Call

Dear Norbert,

As you know, the Target Validation Consortium recently brought together leading academics and industry representatives to develop detailed research plans in four disease areas. We are enthusiastic that the proposals will help us find more efficient routes to validate drug targets, reversing the current trend of costly late-stage failures.

I am happy to announce that the NIH is pledging significant support for each project across all disease areas. We have committed to funding 50% of the total research costs and have the full support of the Directors of NIMH, NIA, NIDDK, NIAMS, and NIAID.

I would like to briefly discuss this with you early next week; I don't expect the phone call to take more than 10 minutes. Please have your assistant contact Gretchen or Ayanna to schedule a convenient time to chat.

I look forward to hearing from you soon.

Best regards, Francis

## Target Validation ConsortiumOverview

July 2013

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From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 28 Jun 2013 11:18:29 +0000

To: Hodes, Richard (NIH/NIA) [E]

Subject: RE: Target Validation Check-in

Points well taken. (b) (5)

FC

From: Hodes, Richard (NIH/NIA) [E]
Sent: Friday, June 28, 2013 6:37 AM
To: Collins, Francis (NIH/OD) [E]
Subject: FW: Target Validation Check-in

Hi Francis,

Some points in the proposed TVC governance give me pause. As we discussed, NIA participation would be via funding of soon to be awarded clinical trials with extensive biomarkers. Given, this, I am not sure how the points copied below from the TVC working document would be implemented. Happy to talk at some point.

Thanks Richard



From: Fortune Jennifer [mailto: (b) (6)

Sent: Thursday, June 27, 2013 10:21 AM

To: Ringel Michael; Meltzer, Sherry (NIH/NIAMS) [E]; <a href="mailto:edmonds-pamela\_j@lilly.com">edmonds-pamela\_j@lilly.com</a>; Hudson, Kathy (NIH/OD) [E]; 'richard.lifton@yale.edu'; Brawley, David (NIH/NIDDK) [E]; Sara Ponzo; 'francis.cuss@bms.com'; Wholley, David (FNIH) [T]; Palisch Chase; Collins, Francis (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; 'garry@appletreepartners.com'; Katz, Stephen I. (NIH/NIAMS) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; 'altshuler@molbio.mgh.harvard.edu'; Carter, Robert (NIH/NIAMS) [E]; 'mikael.dolsten@pfizer.com'; 'lundberg\_jan@lilly.com'; Holt, Tracy (NIH/NIMH) [E]; Hodes, Richard (NIH/NIA) [E]; Wagner, Tim; <a href="mailto:debra.zander@bms.com">debra.zander@bms.com</a>; Insel, Thomas (NIH/NIMH) [E]; Bronson, Charlette (NIH/NIA) [E]; Schulke, Hilda (NIH/OD) [E]; Budzinack, Janet; Cairns-Smith Sarah; Stefan Reed

Cc: 'Wendy Ward'

Subject: RE: Target Validation Check-in

TVC Steering Committee,

Please find attached materials for our discussion tomorrow.

You will also find attached the current draft of the pitch deck. The technical groups have updated the disease area content and we are currently updating the front section and hope to finalize by Monday at the latest pending your feedback. Please let us know if you have any suggestions.

Once complete, we will share the final pitch deck and the updated detailed research plans back with the group.

Looking forward to our discussion, Jen & the BCG team Jennifer Fortune Project Leader THE BOSTON CONSULTING GROUP **(b) (6)** \* Mobile (b)(6)----Original Appointment----From: Ringel Michael Sent: Wednesday, March 13, 2013 12:17 PM To: (b) (6); edmonds pamela j@lilly.com; (b) (6) 'richard.lifton@yale.edu'; (b) (6) Sara Ponzo; 'francis.cuss@bms.com'; 'dwholley@fnih.org'; Palisch Chase; (b) (6); 'Wood, Gretchen (NIH/OD) [E]'; garry@appletreepartners.com'; (b) (6); Bloom (Sartorius) Leah; 'altshuler@molbio.mgh.harvard.edu'; Chand Nikhilesh; (b)(6)'mikael.dolsten@pfizer.com'; 'lundberg\_jan@lilly.com'; (b) (6); (b) (6) Wagner, Tim; debra.zander@bms.com; (b)(6)(b) (6) Budzinack, Janet; Cairns-Smith Sarah; Stefan Reed; Fortune Jennifer Cc: 'Wendy Ward'; Piccin, David **Subject:** Target Validation Check-in When: Friday, June 28, 2013 8:00 AM-8:30 AM (UTC-05:00) Eastern Time (US & Canada). Where: ID: (b) (6), Phone: +( When: Occurs every Friday effective 2/1/2013 until 8/30/2013 from 8:00 AM to 8:30 AM (UTC-05:00) Eastern Time (US & Canada). Where: ID: (b) (6), Phone: +

6/13 – extending the Friday TVC check-ins through August.

\*~\*~\*~\*~\*~\*~\*~\*

Note: The GMT offset above does not reflect daylight saving time adjustments.

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Blackberry quick dial-in: iPhone quick dial-in: + (b)(6)

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From: Collins, Francis (NIH/OD) [E]

Sent: Wed, 5 Jun 2013 13:59:08 +0000

To: Andrew.Plump@sanofi.com

Subject: RE: Touching Base on a TVC thought

Hi Andy,

Thanks for your follow up. David Altshuler is here for a couple of days, and I will also ask him about the (b) (4) — it would certainly be a shame to miss out on potential synergies.

Best, Francis

**From:** Andrew.Plump@sanofi.com [mailto:Andrew.Plump@sanofi.com]

Sent: Wednesday, June 05, 2013 12:02 AM

To: Collins, Francis (NIH/OD) [E]

Subject: RE: Touching Base on a TVC thought

Hi Francis,

Thanks. Let's keep pushing forward on these important activities. Given the robustness of the proposals and their importance to our collective mission, let's continue to talk openly about how best to move them forward.

(b) (4)

If they are helpful in the future, I would be glad to share more.

Please take my reaching out in its intended spirit of sharing your vision and wanting to give it every shot at moving forward.

Thanks for leading moving this effort forward with such determination and passion.

Andy

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Monday, June 03, 2013 12:36 PM

To: Plump, Andrew R&D/FR

Subject: RE: Touching Base on a TVC thought

Hi Andy,

Thanks for your note.

(b) (4)

(b) (4)

| We should definitely keep this in mind going forward!                                                                                                                           |         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| Best, Francis                                                                                                                                                                   |         |
| From: Andrew.Plump@sanofi.com [mailto:Andrew.Plump@sanofi.com]  Sent: Sunday, June 02, 2013 1:14 PM  To: Collins, Francis (NIH/OD) [E]  Subject: Touching Base on a TVC thought |         |
| Hi Francis,                                                                                                                                                                     |         |
| Very much looking forward to our TVC discussion on Thursday.                                                                                                                    |         |
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| If you would like to discuss this further please let me know, or we can see how the discussion proceeds on Thursday and go from there.                                          |         |
| Thanks,<br>Andy                                                                                                                                                                 |         |
| PS I've not discussed this yet with Elias, who I know is very supportive of your vision.                                                                                        |         |
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From: Collins, Francis (NIH/OD) [E]
Sent: Fri, 4 Oct 2013 17:59:14 +0000

To: Chin, Bill

Cc: Cush, Ronda; Mikael Dolsten

Subject: RE: TV Consortium

I'd be glad to talk -- how about now? Phone number?

----Original Message----

From: Chin, Bill [mailto:Chin@phrma.org]
Sent: Friday, October 04, 2013 1:44 PM
To: Collins, Francis (NIH/OD) [E]
Ce: Cush, Ronda; Mikael Dolsten

Subject: TV Consortium

Francis, (b) (6) I write to ask whether you can speak to me for a few moments about the status of the TVC and update your efforts to engage the companies. I spoke in-person to Mikael Dohlsten yesterday who suggested that you've made significant progress. I'd like to chat to learn how PhRMA can help. Bill

From: Collins, Francis (NIH/OD) [E]

Sent: Wed, 30 Oct 2013 00:27:18 +0000

To: Hodes, Richard (NIH/NIA) [E]

Subject: RE: TVC - AD Steering Committee

Hi Richard,

That is very encouraging news. Yes, please introduce me to John tomorrow AM.

FC

From: Hodes, Richard (NIH/NIA) [E]
Sent: Tuesday, October 29, 2013 7:17 PM
Tax Calling, Francis (NIH/OD) [E]

To: Collins, Francis (NIH/OD) [E]

Subject: FW: TVC - AD Steering Committee

### Hi Francis,

I had the opportunity to spend 2.5 hours with

(b) (5)

If you would like to meet him at Natcher tomorrow morning, I can try to connect the two of you.

Thanks Richard

From: Palisch Chase [mailto: (b) (6)

Sent: Tuesday, October 29, 2013 9:37 AM

**To:** Hodes, Richard (NIH/NIA) [E] **Cc:** Buckholtz, Neil (NIH/NIA) [E]

Subject: RE: TVC - AD Steering Committee

Hi Richard,

Attached you will find materials for tomorrow's TVC AD Steering Committee meeting. They include the discussion materials as well as the materials Neil sent through this weekend on NIA funded initiatives.

We've sent the materials to the rest of the Steering Committee and look forward to discussing tomorrow. Please let me know if you have any questions in the meantime.

Thanks, Chase

Chase Palisch
THE BOSTON CONSULTING GROUP
Tel. +1 (b) (6) • Mobile (b) (6)

----Original Appointment----From: Palisch Chase Sent: Wednesday, October 23, 2013 9:24 AM To: 'charlie.albright@bms.com'; 'Buckholtz, Neil (NIH/NIA) [E]'; 'xiaoming.x.guan@gsk.com'; 'tim.harris@biogenidec.com'; 'Michael Leslie Hutton'; (b) (6); John. Alam@sanofi.com; 'mcarrillo@alz.org'; Wholley, David (FNIH) [T]; Cheryl Melencio; 'jeanne.ellice@bms.com'; 'weaverd2@mail.nih.gov'; 'cathy.y.chen@gsk.com'; 'Kathleen.kelley@biogenidec.com'; 'jones\_donna\_a@lilly.com'; 'Denise Goldback'; (b) (6); Hoffmann, Steve (FNIH) [T]; Decker, Michael W Cc: Ringel Michael; Cairns-Smith Sarah; Christine Maisano Subject: TVC - AD Steering Committee When: Wednesday, October 30, 2013 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada). Where: ID: (b) (6) , Phone: Mobile phone link: (b)(6)(b) (6) Blackberry quick dial-in: iPhone quick dial-in: + (b)(6)(b)(6)Passcode: To manually attend the Voice Conference: 1. Dial into MeetMe (In-office speed dial: (b) (6)) 2. Enter the Passcode followed by the # sign Important commands \*0 Operator assistance (also in case of quality issues) #0 Conference help menu Global Access Numbers & Additional commands Dial-in Numbers: Country Number Argentina +54 1153541176 Australia +61 280318145 Austria +43 1206091303 Bahrain 80004629 Belgium +32 22008540 Brazil +55 11 4700 1524 Brazil (Toll-free) 08000474988 Canada (Toll-free) +18774826140 Chile (Toll-free) 800395032 China +86 4008811648 China (Beijing) +86 10 8527 9944 China (Shanghai) +86 21 2082 3005 Colombia (Toll-free) 018000129898 Croatia (Toll-free) 0800777982 Cyprus (Toll-free)

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| From:<br>Sent:<br>To:<br>Subject:                                                                          | Collins, Francis (NIH/OD) [E] Thu, 11 Jul 2013 17:25:18 +0000 Bloom (Sartorius) Leah RE: TVC - follow-up                                                                                                                                                                      |                                 |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Dear Leah,                                                                                                 |                                                                                                                                                                                                                                                                               |                                 |
|                                                                                                            | ote. Your expert assistance in the design phase of the TVC was mormal input in the next steps – which I'm hoping will actually hap                                                                                                                                            |                                 |
| Thanks also for your kin conversation between                                                              | nd note about the book. It was gratifying to know that this could (b) (6)                                                                                                                                                                                                     | l help illuminate a             |
| Warm regards, Francis                                                                                      |                                                                                                                                                                                                                                                                               |                                 |
| From: Bloom (Sartorius<br>Sent: Thursday, July 11<br>To: Collins, Francis (NII-<br>Subject: TVC - follow-u | 1, 2013 8:18 AM<br>H/OD) [E]                                                                                                                                                                                                                                                  |                                 |
| Francis,                                                                                                   |                                                                                                                                                                                                                                                                               |                                 |
| I wanted to follow up w                                                                                    | rith you on our collaboration during the "design phase" of the TV                                                                                                                                                                                                             | /C.                             |
| Chase taking the reins diproject on an important                                                           | ormal involvement in the project has come to a close, with Mich<br>during this next phase of our work together. I will say that this is<br>t, pressing topic — one of my most rewarding experiences while a<br>rd to staying connected to the work on an informal basis going | a very exciting working at BCG. |
| On a more personal not                                                                                     | te –                                                                                                                                                                                                                                                                          | (b) (6)                         |
|                                                                                                            |                                                                                                                                                                                                                                                                               |                                 |
| Thanks again for the col                                                                                   | llaboration, and I look forward to staying in touch.                                                                                                                                                                                                                          |                                 |
| All the best,<br>Leah                                                                                      |                                                                                                                                                                                                                                                                               |                                 |
| Leah Bloom, PhD<br>Principal                                                                               |                                                                                                                                                                                                                                                                               |                                 |

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| ssistar | t: Katherine Kingman |         |  |
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| el      | (b) (6)              | (b) (6) |  |

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From: Collins, Francis (NIH/OD) [E]

Sent: Wed, 25 Sep 2013 05:48:18 +0000

To: Hudson, Kathy (NIH/OD) [E]

Cc: Jorgenson, Lyric (NIH/OD) [E]

Subject: RE: TVC "governance" plans

Yes, I see the struggle – but it really helps to have these two concrete examples. Some of this is more about style than substance.

(b) (5)

I agree with your three mechanisms for various stages of the partnership (below) – and would hope that the next iteration of David's plans could incorporate more of that spirit.

This is pretty hard to work out by e-mail, and I'm concerned that the TVC SC is expecting some sort of proposed plan on Friday, and October 2 is looming. My schedule this week is a wreck, but is there any chance that you, David, and I could meet at 6:15 PM tomorrow? Meanwhile, if you and he could generate a new version, that would be great.

FC

From: Hudson, Kathy (NIH/OD) [E]

Sent: Tuesday, September 24, 2013 4:52 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]

Subject: FW: TVC "governance" plans

#### Francis,

Still really struggling with TVC plans. It feels like industry and academic scientists worked really collaboratively to develop the white papers and now we are dividing up what each group will do. David developed the attached which comes across as "nih will do what it wants and industry can contribute." Even the section headers send the wrong messages. They would be better as "nih role" and "industry role."



From: Wholley, David (FNIH) [T]

Sent: Tuesday, September 24, 2013 12:13 PM

**To:** Hudson, Kathy (NIH/OD) [E] **Subject:** TVC "governance" plans

### Kathy -

Nice to see you last night. I have put together draft governance and next steps for at least the two disease areas that represent the extremes of readiness for TVC launch—Alzheimer's and RA/lupus. I have a call in to Phil Smith to talk about diabetes and can produce something along these lines for that area once we have spoken. I tried to make these as detailed as possible—we can decide how to present them, graphics etc. later, but I wanted to make sure we understand/agree the nuts and bolts before we go back to Francis. I understand you have some thoughts from your internal NIH discussions. Let me know when you want to talk so we can merge and adjust. David

#### **David Wholley**

Director, The Biomarkers Consortium
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 594-6343 | Fax (301) 480-2752

Combined Federal Campaign (CFC) #29165 Recipient of 4-star rating from Charity Navigator, 2007-2011



From: Collins, Francis (NIH/OD) [E]
Sent: Fri, 25 Oct 2013 17:59:57 +0000

To: Cuss, Francis
Subject: RE: TVC & PhRMA

I'm free today between 5 and 6 PM, would that work? Call my cell

(b) (6)

**From:** Cuss, Francis [mailto:francis.cuss@bms.com]

**Sent:** Friday, October 25, 2013 1:48 PM **To:** Collins, Francis (NIH/OD) [E]

Subject: TVC & PhRMA

Francis.

I'm sorry I couldn't make the call this morning.

I've struggled this week to find a time to discuss with my Industry colleagues, but I think I know enough of their views to provide you with some insight and advice.

Would you have 5 minutes (literally) to chat by telephone later today or next week.

Best, Francis

This message (including any attachments) may contain confidential, proprietary, privileged and/or private information. The information is intended to be for the use of the individual or entity designated above. If you are not the intended recipient of this message, please notify the sender immediately, and delete the message and any attachments. Any disclosure, reproduction, distribution or other use of this message or any attachments by an individual or entity other than the intended recipient is prohibited.

Collins, Francis (NIH/OD) [E] From: Sent: Fri, 9 Aug 2013 13:00:14 +0000 To: Hudson, Kathy (NIH/OD) [E]

Subject: RE: Tvc

You've got to be kidding

----Original Message----

From: Hudson, Kathy (NIH/OD) [E] Sent: Friday, August 09, 2013 7:52 AM To: Collins, Francis (NIH/OD) [E]

Subject: Tvc

I will not be on call.

(b) (5)

Kathy Hudson, Ph.D.

Deputy Director for Science, Outreach, and Policy NIH
(b) (6)

| Sent: Sun, 14 Jul 2013 22:21:55 + 0.000 To: Katz, Stephen I. (NIH/NIAMS) [E] Cc: Carter, Robert (NIH/NIAMS) [E] Subject: RE: TVC  It was a blast all right. But a band with 14 members and very few rehearsals really stretches the ability to start and end together!   From: Katz, Stephen I. (NIH/NIAMS) [E] Sent: Sunday, July 14, 2013 4:44 PM To: Collins, Francis (NIH/DD) [E] Cc: Carter, Robert (NIH/NIAMS) [E] Subject: Re: TVC  Sure- Sorry I missed you last night- heard it was a blast.  Steve  Sent from my iPhone  On Jul 14, 2013, at 2:22 PM, "Collins, Francis (NIH/OD) [E]"  ### Bistory  #### Bistory  ### Bistory  ### Bistory  #### Bistory | From:                                                      | Collins, Francis (NIH/OD) [E]                                  |                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|----------------------------------------------------------------|----------------------------|
| Cc: Carter, Robert (NIH/NIAMS) [E] Subject: RE: TVC  It was a blast all right. But a band with 14 members and very few rehearsals really stretches the ability to start and end together!   From: Katz, Stephen I. (NIH/NIAMS) [E] Sent: Sunday, July 14, 2013 4:44 PM To: Collins, Francis (NIH/NIAMS) [E] Cc: Carter, Robert (NIH/NIAMS) [E] Subject: Re: TVC  Sure- Sorry I missed you last night- heard it was a blast.  Steve Sent from my iPhone  On Jul 14, 2013, at 2:22 PM, "Collins, Francis (NIH/OD) [E]"  On Jul 14, 2013, at 2:22 PM, "Collins, Francis (NIH/OD) [E]"  FC  From: Katz, Stephen I. (NIH/NIAMS) [E] Sent: Friday, July 12, 2013 11:30 AM To: Collins, Francis (NIH/OD) [E] Cc: Carter, Robert (NIH/NIAMS) [E] Subject: TVC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                            |                                                                |                            |
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| Steve  Sent from my iPhone  On Jul 14, 2013, at 2:22 PM, "Collins, Francis (NIH/OD) [E]"  (b) 6) wrote:  Hi Steve,  FC  From: Katz, Stephen I. (NIH/NIAMS) [E]  Sent: Friday, July 12, 2013 11:30 AM  To: Collins, Francis (NIH/OD) [E]  Cc: Carter, Robert (NIH/NIAMS) [E]  Subject: TVC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                            |                                                                |                            |
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| FC  From: Katz, Stephen I. (NIH/NIAMS) [E] Sent: Friday, July 12, 2013 11:30 AM To: Collins, Francis (NIH/OD) [E] Cc: Carter, Robert (NIH/NIAMS) [E] Subject: TVC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Sent from my i                                             | Phone                                                          |                            |
| FC  From: Katz, Stephen I. (NIH/NIAMS) [E]  Sent: Friday, July 12, 2013 11:30 AM  To: Collins, Francis (NIH/OD) [E]  Cc: Carter, Robert (NIH/NIAMS) [E]  Subject: TVC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | On Jul 14, 2013                                            | B, at 2:22 PM, "Collins, Francis (NIH/OD) [E]"                 | (b) (6) wrote:             |
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| Sent: Friday, July 12, 2013 11:30 AM  To: Collins, Francis (NIH/OD) [E]  Cc: Carter, Robert (NIH/NIAMS) [E]  Subject: TVC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | FC                                                         |                                                                |                            |
| Francis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Sent: Friday, Jul<br>To: Collins, Fran<br>Cc: Carter, Robe | y 12, 2013 11:30 AM<br>cis (NIH/OD) [E]                        |                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Francis                                                    |                                                                | <b>(b)</b> (5)             |

# Steve

Stephen I. Katz, MD, PHD
Director, National Institute of Arthritis and
Musculoskeletal and Skin Diseases
National Institutes of Health
Bldg. 31 Rm. 4C32
Bethesda, MD 20892

NIH ... Turning Discovery Into Health

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Sun, 14 Jul 2013 18:22:13 +0000

 To:
 Katz, Stephen I. (NIH/NIAMS) [E]

 Cc:
 Carter, Robert (NIH/NIAMS) [E]

Subject: RE: TVC

Hi Steve,

FC

(b) (5)

From: Katz, Stephen I. (NIH/NIAMS) [E]
Sent: Friday, July 12, 2013 11:30 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Carter, Robert (NIH/NIAMS) [E]

Subject: TVC

Francis...

## Steve

Stephen I. Katz, MD, PHD
Director, National Institute of Arthritis and
Musculoskeletal and Skin Diseases
National Institutes of Health
Bldg. 31 Rm. 4C32
Bethesda, MD 20892

NIH ... Turning Discovery Into Health

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 11 Jul 2013 16:52:33 +0000

 To:
 Katz, Stephen I. (NIH/NIAMS) [E]

 Cc:
 Fauci, Anthony (NIH/NIAID) [E]

Subject: RE: TVC

Fantastic!!! Many thanks to you both,

Francis

From: Katz, Stephen I. (NIH/NIAMS) [E]
Sent: Thursday, July 11, 2013 12:15 PM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Fauci, Anthony (NIH/NIAID) [E]

Subject: TVC

# Hi Francis,

Tony and I had a chat about the target validation initiative and we are prepared to jointly support up to 4M\$ per year for this effort depending, of course, on what funds come from industry. We are happy to discuss this further if you wish.

At this point there are no specific projects that we can put forward that would count as "in kind" by the definitions that are being used for this endeavor.

# Steve

### Steve Katz

Stephen I. Katz, MD, PHD
Director, National Institute of Arthritis and
Musculoskeletal and Skin Diseases
National Institutes of Health
Bldg. 31 Rm. 4C32
Bethesda, MD 20892

# NIH ... Turning Discovery Into Health

From:

Collins, Francis (NIH/OD) [E]

Sent:

Fri, 21 Jun 2013 12:39:43 +0000

To:

Hodes, Richard (NIH/NIA) [E]

Subject:

Re: TVC

Yes! That's the meeting we are having this coming Tuesday.

Sent from my iPhone

On Jun 21, 2013, at 8:27 AM, "Hodes, Richard (NIH/NIA) [E]"

(b) (6)

wrote:

Hi Francis,

**(b) (5)** 

Thanks Richard 
 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 26 Sep 2013 09:14:08 +0000

 To:
 Hudson, Kathy (NIH/OD) [E]

 Cc:
 Jorgenson, Lyric (NIH/OD) [E]

Subject: RE: tvc alert!!!

Yes, I sent a note to all of the academic members of the white paper groups, telling them we were going on to the next phase and they should opt out if they thought they might want to apply. See below – we had agreed this needed to be done in the last call or two. The mistake was not ccing you, Richard, Griff, and Bob.

From: Collins, Francis (NIH/OD) [E]

Sent: Tuesday, September 24, 2013 8:46 PM

To: Wood, Gretchen (NIH/OD) [E]

Subject: RE: TVC - Sending letters to prevent conflict of interest

Looks fine, please send out.

From: Wood, Gretchen (NIH/OD) [E]

Sent: Tuesday, September 24, 2013 1:54 PM

To: Collins, Francis (NIH/OD) [E]

Subject: FW: TVC - Sending letters to prevent conflict of interest

FC—just want to be sure you are good with this before I send out anything. Thanks.

g

From: Palisch Chase [mailto:F (b) (6)

Sent: Tuesday, September 24, 2013 1:49 PM

To: Wood, Gretchen (NIH/OD) [E]

Subject: TVC - Sending letters to prevent conflict of interest

Dear Gretchen,

During last week's Target Validation Consortium check-in, Dr. Collins agreed to send out emails to the academic members of the consortium giving them the opportunity to excuse themselves from participation to prevent any conflicts of interest.

I have attached the form email below and the contact details for each member above. Can you help send these on Dr. Collins's behalf from his account?

Please let me know if you have any questions and I will be happy to provide more information.

Thanks,

Chase

\*\*\*DRAFT EMAIL\*\*\* (b)(5)Chase Palisch THE BOSTON CONSULTING GROUP 4800 Hampden Lane, Suite 400 Bethesda, Maryland 20814 - United States

The Boston Consulting Group, Inc.

(b) (6)

Tel.

(b) (6) \* Mobile \*

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mail or any information contained in the message. If you have received this material in error, please advise the sender immediately by reply e-mail and delete this message. Thank you.

From: Hudson, Kathy (NIH/OD) [E]

Sent: Wednesday, September 25, 2013 10:19 PM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Jorgenson, Lyric (NIH/OD) [E]

Subject: tvc alert!!!

Both Richard and Griff told me today that they have gotten many emails today from folks involved in the white paper generation saying that they want to be recused. It would appear that some email went to the entire tvc group that caused this group reaction.



Kathy L. Hudson, Ph.D.
Deputy Director for Science, Outreach, and Policy
National Institutes of Health





<u>Celebration of Science at NIH</u>: watch how medical research saves lives and improves health

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 26 Sep 2013 09:24:09 +0000

 To:
 Hudson, Kathy (NIH/OD) [E]

Cc: Wholley, David (FNIH) [T]; Jorgenson, Lyric (NIH/OD) [E]

Subject: RE: TVC governance flowchart

Looking good. A couple of suggestions if you have time:

(b)(5)

Let's try it out at 10 AM.

FC

From: Hudson, Kathy (NIH/OD) [E]

Sent: Wednesday, September 25, 2013 9:42 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Wholley, David (FNIH) [T]; Jorgenson, Lyric (NIH/OD) [E]

Subject: TVC governance flowchart

Here you go!

Also, we have steve, Richard, and bob for call tomorrow. Griff has council but I talked to him by phone tonight and he seemed to be on board but we should remember to send him the chart and seek his input specifically after the call tomorrow.

From: Collins, Francis (NIH/OD) [E] Sent: Thu, 26 Sep 2013 11:30:12 +0000 Hudson, Kathy (NIH/OD) [E] To:

Cc: Wholley, David (FNIH) [T]; Jorgenson, Lyric (NIH/OD) [E]

Subject: RE: TVC governance flowchart

(b)(5)From: Hudson, Kathy (NIH/OD) [E] Sent: Thursday, September 26, 2013 7:09 AM To: Collins, Francis (NIH/OD) [E] Cc: Wholley, David (FNIH) [T]; Jorgenson, Lyric (NIH/OD) [E] Subject: Re: TVC governance flowchart (b)(5)(b) (5) it draft, and i can send out before call Kathy Hudson, Ph.D. Deputy Director for Science, Outreach, and Policy

NIH

(b) (6)

On Sep 26, 2013, at 5:24 AM, "Collins, Francis (NIH/OD) [E]" (b) (6) wrote:

Looking good. A couple of suggestions if you have time:

(b)(5)

Let's try it out at 10 AM.

FC

From: Hudson, Kathy (NIH/OD) [E]

Sent: Wednesday, September 25, 2013 9:42 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Wholley, David (FNIH) [T]; Jorgenson, Lyric (NIH/OD) [E]

Subject: TVC governance flowchart

# Here you go!

Also, we have steve, Richard, and bob for call tomorrow. Griff has council but I talked to him by phone tonight and he seemed to be on board but we should remember to send him the chart and seek his input specifically after the call tomorrow.

From: Collins, Francis (NIH/OD) [E]
Sent: Wed, 2 Oct 2013 09:33:26 +0000

To: Sullivan - Cvp, James P

Cc: Palisch Chase (b) (6)

Subject: RE: TVC Meeting Tomorrow

Thanks for your note, Jim. This is indeed a trying time. I'm hoping that the TVC call goes well today – I am quite excited about the potential for this collaboration.

Regards, Francis

From: Sullivan - Cvp, James P [mailto:james.p.sullivan@abbvie.com]

Sent: Tuesday, October 01, 2013 9:50 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** TVC Meeting Tomorrow

Dear Francis,

I am travelling tomorrow and unable to attend the TVC meeting. AbbVie remains interested in the RA/SLE workstream and Lisa Olson (Head of our Immunology group) will be on the call. I look forward to seeing the updated research proposal and getting the work off the ground.

On a different note, I heard your comments on the impact of the Govt shut down on the NIH as I was driving home. It is incredibly disheartening to know that patients are being impacted in a significant way. I know that this must be a very trying time for you and many colleagues at the NIH. Please know that your tireless advocacy for patients and scientists is much appreciated by myself and countless other researchers.

Best regards,

Jim

JIM SULLIVAN, PH.D.

Vice President Discovery



#### **AbbVie**

Dept. R473, AP9-1 1 North Waukegan Road North Chicago, IL 60064 OFFICE +1 847-938-3689

CELL

(b) (6)

# EMAIL james.p.sullivan@abbvie.com

# abbvie.com

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 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Tue, 27 Aug 2013 19:36:27 +0000

 To:
 Smith, Philip (NIH/NIDDK) [E]

Cc: Green, Eric (NIH/NHGRI) [E];Guyer, Mark (NIH/NHGRI) [C];Wood, Gretchen

(NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]

Subject: RE: TVC Portal conversation

Perhaps we could all get on the phone soon? I'm ccing Gretchen to ask her to find a time.

FC

From: Smith, Philip (NIH/NIDDK) [E]
Sent: Tuesday, August 27, 2013 3:11 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Green, Eric (NIH/NHGRI) [E]; Guyer, Mark (NIH/NHGRI) [E]

Subject: TVC Portal conversation

Griff forwarded your message and asked me to talk to you about this since he is on leave. He also indicated that Mark should be brought in to the discussion. I forwarded the TVC T2D white paper and your slide set from the June 25 meeting to Mark and had a brief conversation with him to give him some background. Please let me know when and how you would like to discuss this.

Thanks, Phil Smith

From: "Collins, Francis (NIH/OD) [E]" (b) (6)

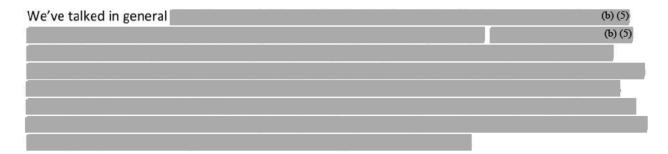
Date: August 25, 2013, 9:13:23 AM EDT

To: "Rodgers, Griffin (NIH/NIDDK) [E]" (b) (6)

Cc: "Green, Eric (NIH/NHGRI) [E]" (b) (6)

Subject: TVC and BD2K

Hi Griff,



Can you, Eric, and I have a conversation about how to make the most of this opportunity?

Francis

Philip F. Smith, Ph.D.
Deputy Director
Division of Diabetes, Endocrinology, and Metabolic Diseases
Co-Director, Office of Obesity Research
National Institute of Diabetes and Digestive and Kidney Diseases
6707 DEMOCRACY BLVD RM 689 MSC5460
BETHESDA MD 20892-5460

phone: (b) (6) FAX: 301.435.6047 e-mail: (b) (6) From: Collins, Francis (NIH/OD) [E]
Sent: Wed, 28 Aug 2013 17:57:25 +0000

To: Smith, Philip (NIH/NIDDK) [E]; Wood, Gretchen (NIH/OD) [E]

Cc: Green, Eric (NIH/NHGRI) [E];Guyer, Mark (NIH/NHGRI) [C];McManus, Ayanna

(NIH/OD) [E];Sante, Annette (NIH/NHGRI) [C]

Subject: RE: TVC Portal conversation

#### And for me

From: Smith, Philip (NIH/NIDDK) [E]

Sent: Wednesday, August 28, 2013 12:59 PM

To: Wood, Gretchen (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]

Cc: Green, Eric (NIH/NHGRI) [E]; Guyer, Mark (NIH/NHGRI) [E]; McManus, Ayanna (NIH/OD) [E]; Sante,

Annette (NIH/NHGRI) [C]

Subject: RE: TVC Portal conversation

This works for me.

Philip F. Smith, Ph.D.
Deputy Director
Division of Diabetes, Endocrinology, and Metabolic Diseases
Co-Director, Office of Obesity Research
National Institute of Diabetes and Digestive and Kidney Diseases
6707 DEMOCRACY BLVD RM 689 MSC5460
BETHESDA MD 20892-5460

phone: (b) (6) FAX: 301.435.6047 e-mail: (b) (6)

From: Wood, Gretchen (NIH/OD) [E]

Sent: Wednesday, August 28, 2013 12:48 PM

To: Smith, Philip (NIH/NIDDK) [E]; Collins, Francis (NIH/OD) [E]

Cc: Green, Eric (NIH/NHGRI) [E]; Guyer, Mark (NIH/NHGRI) [E]; McManus, Ayanna (NIH/OD) [E]; Sante,

Annette (NIH/NHGRI) [C]

Subject: RE: TVC Portal conversation

Will this Friday, August 30 from 9:00 AM to 9:30 AM work? We have a lot of flexibility on Friday so please feel free to offer other times that day if this doesn't work. Thanks.

From: Smith, Philip (NIH/NIDDK) [E] Sent: Tuesday, August 27, 2013 7:41 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Green, Eric (NIH/NHGRI) [E]; Guyer, Mark (NIH/NHGRI) [E]; Wood, Gretchen (NIH/OD) [E];

McManus, Ayanna (NIH/OD) [E] **Subject:** Re: TVC Portal conversation

Gretchen, I have a meeting from 10-11 am tomorrow that I have to attend. Otherwise, I can make myself available anytime. On Thursday I have a meeting from 9-12 that I need to attend but can adapt to

availability of others for any other times.

From: Collins, Francis (NIH/OD) [E]

Sent: Tuesday, August 27, 2013 03:36 PM Eastern Standard Time

To: Smith, Philip (NIH/NIDDK) [E]

Cc: Green, Eric (NIH/NHGRI) [E]; Guyer, Mark (NIH/NHGRI) [E]; Wood, Gretchen (NIH/OD) [E];

McManus, Ayanna (NIH/OD) [E] **Subject**: RE: TVC Portal conversation

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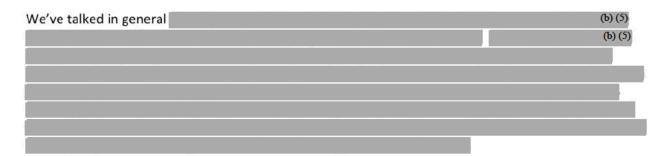
Date: August 25, 2013, 9:13:23 AM EDT

To: "Rodgers, Griffin (NIH/NIDDK) [E]" (b) (6)

Cc: "Green, Eric (NIH/NHGRI) [E]" (b) (6)

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Francis

Philip F. Smith, Ph.D.
Deputy Director
Division of Diabetes, Endocrinology, and Metabolic Diseases
Co-Director, Office of Obesity Research
National Institute of Diabetes and Digestive and Kidney Diseases
6707 DEMOCRACY BLVD RM 689 MSC5460
BETHESDA MD 20892-5460

phone: (b) (6) FAX: 301.435.6047 e-mail: (b) (6)

| From: Sent: To: Cc: Subject:                           | Collins, Francis (NIH/OD) [E] Mon, 30 Sep 2013 21:35:35 +0000 Carter, Robert (NIH/NIAMS) [E] Katz, Stephen I. (NIH/NIAMS) [E];Hudson, Kathy (NIH/OD) [E] RE: TVC RA SLE gov.pptx draft |                 |
|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Hi Bob,                                                |                                                                                                                                                                                        |                 |
| I see what you a                                       | re driving at —                                                                                                                                                                        | (b) (5)         |
|                                                        |                                                                                                                                                                                        |                 |
| Francis                                                |                                                                                                                                                                                        |                 |
| Sent: Monday, S<br>To: Hudson, Kat<br>Cc: Katz, Stephe | obert (NIH/NIAMS) [E]<br>September 30, 2013 2:55 PM<br>thy (NIH/OD) [E]<br>en I. (NIH/NIAMS) [E]; Collins, Francis (NIH/OD) [E]<br>A SLE gov.pptx draft                                |                 |
| Hi Kathy                                               |                                                                                                                                                                                        |                 |
| The RA/SLE team                                        | n worked on the draft governance chart.                                                                                                                                                | (b) (5)         |
|                                                        | the updated version, so let me know your comments and suggestion, and e are in agreement.                                                                                              | then I will get |
| _0 0                                                   |                                                                                                                                                                                        |                 |

**Thanks** 

Bob

| From: Sent: To: Cc: (NIH/OD) [E];Hodes, Ri [E];Rodgers, Griffin (NI Subject:                                     | Collins, Francis (NIH/OD) [E] Sat, 21 Sep 2013 03:33:57 +0000 Palisch Chase Cairns-Smith Sarah;Ringel Michael;Wholley, David (FNIH) [T];Hudson, Kathy ichard (NIH/NIA) [E];Katz, Stephen I. (NIH/NIAMS) [E];Carter, Robert (NIH/NIAMS) [H/NIDDK) [E] RE: TVC reminder to Elias Zerhouni |       |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| Jubject.                                                                                                         | RE. I Ve Terminder to Elias Zerriodin                                                                                                                                                                                                                                                   |       |
| Hi all,                                                                                                          |                                                                                                                                                                                                                                                                                         |       |
| speak with him directly                                                                                          | f progress at two years in order to decide whether to go forward for five. I told                                                                                                                                                                                                       |       |
| So put them down in the                                                                                          | he YES column.                                                                                                                                                                                                                                                                          |       |
| FC                                                                                                               |                                                                                                                                                                                                                                                                                         |       |
| From: Palisch Chase [ Sent: Friday, Septemb To: Collins, Francis (NI Cc: Cairns-Smith Sarah Subject: TVC reminde | per 20, 2013 5:45 PM<br>[H/OD) [E]<br>n; Ringel Michael                                                                                                                                                                                                                                 |       |
| Hi Francis,                                                                                                      |                                                                                                                                                                                                                                                                                         |       |
| management of an experience of the second of the                                                                 | g to send a reminder to Elias. Hopefully we can get Sanofi's commitment to the at they can participate in the October 2nd meeting.                                                                                                                                                      |       |
| We have included a brifit.                                                                                       | ief note below for you to follow up. Obviously, feel free to edit and use as you see                                                                                                                                                                                                    |       |
| Thanks again,<br>Chase                                                                                           |                                                                                                                                                                                                                                                                                         |       |
| ****                                                                                                             |                                                                                                                                                                                                                                                                                         |       |
|                                                                                                                  |                                                                                                                                                                                                                                                                                         | (b) ( |
|                                                                                                                  |                                                                                                                                                                                                                                                                                         |       |
|                                                                                                                  |                                                                                                                                                                                                                                                                                         |       |

| Best rega              | ards,                                                                   |  |  |
|------------------------|-------------------------------------------------------------------------|--|--|
| Francis                |                                                                         |  |  |
| Chase Pa               | lisch                                                                   |  |  |
|                        | ON CONSULTING GROU<br>oden Lane, Suite 400<br>Maryland 20814 • United S |  |  |
| 4800 Hami<br>Bethesda, | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,                                 |  |  |

(b) (4)

The Boston Consulting Group, Inc.

This e-mail message may contain confidential and/or privileged information. If you are not an addressee or otherwise authorized to receive this message, you should not use, copy, disclose or take any action based on this e-mail or any information contained in the message. If you have received this material in error, please advise the sender immediately by reply e-mail and delete this message. Thank you.

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 22 Nov 2013 09:46:20 +0000

 To:
 Katz, Stephen I. (NIH/NIAMS) [E]

 Cc:
 Carter, Robert (NIH/NIAMS) [E]

Subject: RE: TVC reminder

Yes, I spoke with David, and we can bring this up on the phone this morning.

Best, Francis

From: Katz, Stephen I. (NIH/NIAMS) [E]
Sent: Thursday, November 21, 2013 10:47 PM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Carter, Robert (NIH/NIAMS) [E]

Subject: TVC reminder

# Hi Francis-

(b) (5)

As you know,

we are having a face to face on December the 4<sup>th</sup> and the industry people will, no doubt, want to know what their respective obligations will be. I am happy to do this but it seems better that you get the big picture for all three initiatives-

# Steve

Steve Katz
Stephen I. Katz, MD, PHD
Director, National Institute of Arthritis and
Musculoskeletal and Skin Diseases
National Institutes of Health
Bldg. 31 Rm. 4C32
Bethesda, MD 20892

NIH... Turning Discovery Into Health

From: Collins, Francis (NIH/OD) [E]

Sent: Mon, 1 Jul 2013 19:25:22 +0000

To: Hudson, Kathy (NIH/OD) [E]

Cc: Devaney, Stephanie (NIH/OD) [E]

Subject: RE: TVC summary 6-29-13

Attachments: TVC summary 6-29-13 fsc.docx

See a few comments.

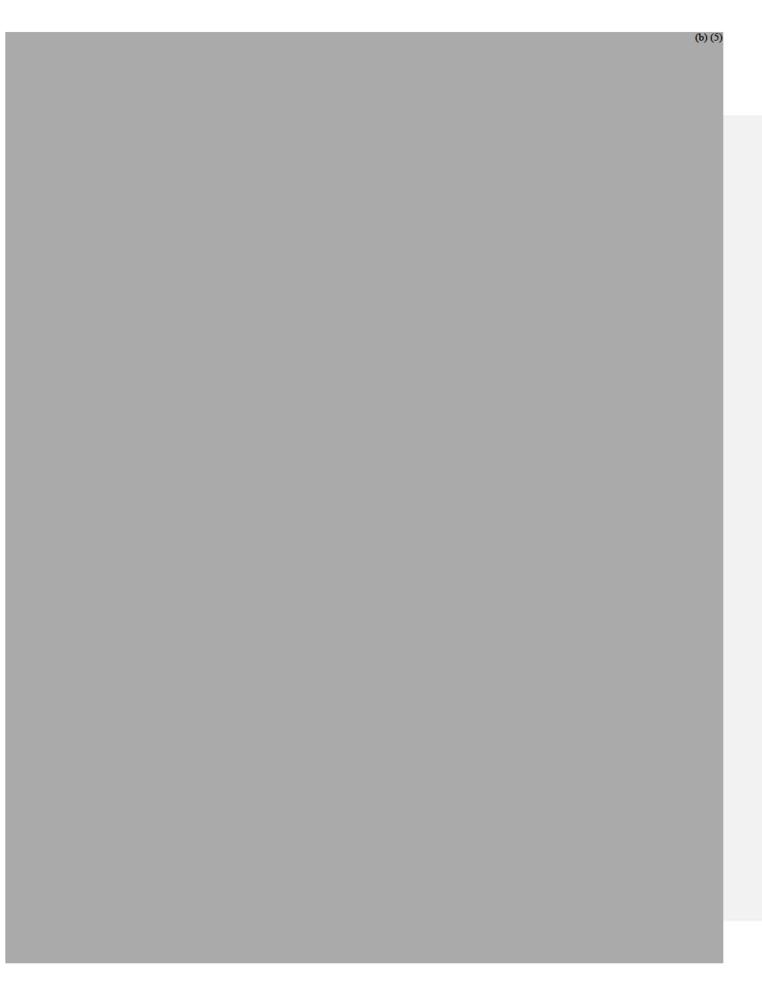
FC

From: Hudson, Kathy (NIH/OD) [E] Sent: Saturday, June 29, 2013 11:59 AM

To: Collins, Francis (NIH/OD) [E]
Cc: Devaney, Stephanie (NIH/OD) [E]
Subject: TVC summary 6-29-13

(b) (5)

Comments welcome on text and next steps.







From: Collins, Francis (NIH/OD) [E]
Sent: Tue, 22 Oct 2013 15:54:50 +0000

To: Freire, Maria (FNIH) [T]

Subject: RE: TVC

That's good, we want to save the big bounce for the WH.

----Original Message----From: Freire, Maria (FNIH) [T]

Sent: Tuesday, October 22, 2013 11:31 AM

To: Collins, Francis (NIH/OD) [E]

Subject: TVC

Francis, Regarding my note on the announcement, the comment was very gentle and well done. Just wanted you to know that there was no preemptive move, on the contrary, an elegant teaser. M.

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Sat, 7 Dec 2013 19:22:02 +0000

 To:
 Dolsten, Mikael:RINGEM01

Cc: Palisch Chase; Hodes, Richard (NIH/NIA) [E]; Rodgers, Griffin (NIH/NIDDK)

[E];lundberg\_jan@lilly.com;Insel, Thomas (NIH/NIMH) [E];Katz, Stephen I. (NIH/NIAMS)

[E];francis.cuss@bms.com;richard.lifton@yale.edu;Hudson, Kathy (NIH/OD) [E];Wholley, David (FNIH) [T];Cairns-Smith Sarah;Carter, Robert (NIH/NIAMS) [E];McManus, Ayanna (NIH/OD) [E];Bronson, Charlette (NIH/NIA) [E];Melencio, Cheryl (FNIH) [T];edmonds\_pamela\_j@lilly.com;Wilkerson, Anita D. (NIH/NIDDK) [E];debra.zander@bms.com;Poole, Charlene (NIH/NIDDK) [E];Holt, Tracy (NIH/NIMH) [E];Meltzer, Sherry (NIH/NIAMS) [E];Schulke, Hilda (NIH/OD) [E];elizabeth.cappello@yale.edu;Brawley,

David (NIH/NIDDK) [E]; Wagner, Tim; Wood, Gretchen (NIH/OD) [E]

Subject: RE: What's in a name?

Thanks for your thoughts on AMP, everyone. It sounds as if we have something here we can work with.

(b) (4)

One possible way to capture the target idea would be a logo that has block letters AMP superimposed on a target icon.

Francis

----Original Message----

From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Friday, December 06, 2013 6:00 PM

To: RINGEM01

Cc: Collins, Francis (NIH/OD) [E]; Palisch Chase; Hodes, Richard (NIH/NIA) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; lundberg\_jan@lilly.com; Insel, Thomas (NIH/NIMH) [E]; Katz, Stephen I. (NIH/NIAMS) [E]; francis.cuss@bms.com; richard.lifton@yale.edu; Hudson, Kathy (NIH/OD) [E]; Wholley, David (FNIH) [T]; Cairns-Smith Sarah; Carter, Robert (NIH/NIAMS) [E]; McManus, Ayanna (NIH/OD) [E]; Bronson, Charlette (NIH/NIA) [E]; Melencio, Cheryl (FNIH) [T]; edmonds\_pamela\_j@lilly.com; Wilkerson, Anita D. (NIH/NIDDK) [E]; debra.zander@bms.com; Poole, Charlene (NIH/NIDDK) [E]; Holt, Tracy (NIH/NIMH) [E]; Meltzer, Sherry (NIH/NIAMS) [E]; Schulke, Hilda (NIH/OD) [E]; elizabeth.cappello@yale.edu; Brawley, David (NIH/NIDDK) [E]; Wagner, Tim; Wood, Gretchen (NIH/OD) [E]

Subject: Re: What's in a name?



| Just some reflections                                                                                 |                |
|-------------------------------------------------------------------------------------------------------|----------------|
| Mikael                                                                                                |                |
| Sent from my iPhone                                                                                   |                |
| On Dec 6, 2013, at 17:27, "RINGEM01"                                                                  | (b) (6) wrote: |
| I love it!                                                                                            |                |
| Michael Ringel, Ph.D. Partner and Managing Director THE BOSTON CONSULTING GROUP Tel.  Mobile  (b) (6) |                |

From: Collins, Francis (NIH/OD) [E] [mailto

Sent: Friday, December 06, 2013 2:50 PM

To: Palisch Chase; Ringel Michael; Hodes, Richard (NIH/NIA) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; 'lundberg\_jan@lilly.com<mailto:lundberg\_jan@lilly.com>'; Insel, Thomas (NIH/NIMH) [E]; Katz, Stephen I. (NIH/NIAMS) [E]; 'francis.cuss@bms.com<mailto:francis.cuss@bms.com>';

'richard.lifton@yale.edu<mailto:richard.lifton@yale.edu>'; Hudson, Kathy (NIH/OD) [E]; Wholley, David (FNIH) [T]; Cairns-Smith Sarah; 'mikael.dolsten@pfizer.com<mailto:mikael.dolsten@pfizer.com>'; Carter, Robert (NIH/NIAMS) [E]

(b) (6)

Cc: McManus, Ayanna (NIH/OD) [E]; Bronson, Charlette (NIH/NIA) [E]; Melencio, Cheryl (FNIH) [T]; edmonds\_pamela\_j@lilly.com<mailto:edmonds\_pamela\_j@lilly.com>; Wilkerson, Anita D. (NIH/NIDDK) [E]; debra.zander@bms.com<mailto:debra.zander@bms.com>; Poole, Charlene (NIH/NIDDK) [E]; Holt, Tracy (NIH/NIMH) [E]; Meltzer, Sherry (NIH/NIAMS) [E]; Schulke, Hilda (NIH/OD) [E]; elizabeth.cappello@yale.edu<mailto:elizabeth.cappello@yale.edu>; Brawley, David (NIH/NIDDK) [E]; tim.wagner@pfizer.com<mailto:tim.wagner@pfizer.com>; Wood, Gretchen (NIH/OD) [E] Subject: What's in a name?

Hi all,

We've had several discussions over the last month about a new name for TVC. Now I'm in a situation where I'd like to see if we can resolve this. I have a chance to describe the consortium to a VERY highly placed member of the Executive Branch on Monday, and I'd like to use a better name if we can agree on one.

After quite a bit of brainstorming around here, the preferred name that has emerged is "Accelerating Medicines Partnership", or AMP. That has the nice property of being both a noun and a verb (we're AMPing up the development of new medicines).

Another possibility was ATP (conveys the sense of higher energy, at least for the biology wonks), "Accelerating Therapeutics Partnership". But there was a major initiative from NIST a few years ago by this name ("Advanced Technology Program") and that might lead to confusion.

Members of Core Steering Committee, what are your reactions to AMP?

Best, Francis

-

The Boston Consulting Group, Inc.

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From: Collins, Francis (NIH/OD) [E]
Sent: Sat, 20 Jul 2013 18:58:14 +0000

To: David Altshuler

Subject: RE: Worried about TVC

Hi David,

Today has been turned a bit upside down – might we try instead for a call tomorrow (Sunday) around 5:30 PM?

Sorry about all of the changes in plan...

FC

From: David Altshuler [mailto:altshuler@molbio.mgh.harvard.edu]

Sent: Saturday, July 20, 2013 11:22 AM To: Collins, Francis (NIH/OD) [E] Subject: Re: Worried about TVC

I can talk this afternoon -- home is (b) (6) and cell is (b) (6)

Best,

david

On Jul 19, 2013, at 10:33 AM, Collins, Francis (NIH/OD) [E] wrote:

Today is a bit insane – how about Saturday afternoon? Anytime between noon and 3 PM would work for me.

**From:** David Altshuler [mailto:altshul@broadinstitute.org]

**Sent:** Friday, July 19, 2013 9:45 AM **To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: Worried about TVC

sorry I missed this -- (b) (6)

happy to talk today or saturday

On Jul 18, 2013, at 7:33 PM, Collins, Francis (NIH/OD) [E] wrote:

Can I call you this evening? Anytime between now and 10 PM would work for me.

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FC

From: Collins, Francis (NIH/OD) [E]
Sent: Sun, 21 Jul 2013 23:01:29 +0000

To: David Altshuler

Subject: RE: Worried about TVC

Hi again David,

I'm guessing that 60 60 and other things made it impossible to speak today. I'd still like 15 minutes on the phone with you about TVC. I'm about to get on a plane 60 60, but could call you tomorrow (Monday) between 7 and 9 AM, or between 4:45 and 5:30 PM. Let me know.

Tx, Francis

From: Collins, Francis (NIH/OD) [E] Sent: Saturday, July 20, 2013 2:58 PM

To: 'David Altshuler'

Subject: RE: Worried about TVC

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Sent: Friday, July 19, 2013 9:45 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: Worried about TVC

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happy to talk today or saturday

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FC

From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 8 Aug 2013 10:33:14 +0000

To: Palisch Chase;Ringel Michael;Holt, Tracy (NIH/NIMH) [E];Wagner,

Tim; 'altshuler@molbio.mgh.harvard.edu'; Carter, Robert (NIH/NIAMS) [E]; Budzinack, Janet; Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Bronson, Charlette (NIH/NIA) [E]; Rodgers, Griffin

(NIH/NIDDK) [E];'francis.cuss@bms.com';Stefan Reed;Meltzer, Sherry (NIH/NIAMS)

[E];debra.zander@bms.com;Schulke, Hilda (NIH/OD) [E];'mikael.dolsten@pfizer.com';Insel, Thomas (NIH/NIMH) [E];edmonds\_pamela\_j@lilly.com;Hodes, Richard (NIH/NIA) [E];Cairns-Smith Sarah;'garry@appletreepartners.com';'richard.lifton@yale.edu';Bloom (Sartorius) Leah;Katz, Stephen I.

(NIH/NIAMS) [E];Sara Ponzo;Hudson, Kathy (NIH/OD) [E];Brawley, David (NIH/NIA/ERP)

[E];'lundberg\_jan@lilly.com';'Wendy Ward'

**Subject:** Report on phone calls

Hi all,

Here's a quick report on calls I have made this week to potential TVC partners. I focused on the rigor and collaborative nature of the process of developing the design, and emphasized NIH's commitment to contributing our part. I used the talking points and answered questions, without doing a specific ask.



Still trying to connect with John Reed (b) (6)

All in all, reasonably encouraging – albeit short of rock solid commitments.

We can discuss further tomorrow morning.

Best wishes to all, Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 22 Aug 2013 16:05:22 +0000

To: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6)

);Palisch Chase (b) (6)

Cc: Hudson, Kathy (NIH/OD) [E]
Subject: summary of recent TVC calls

Hi all,



Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 16 Aug 2013 20:38:48 +0000

To: 'nbischofberger@gilead.com'

Cc: 'Traci.Carrithers@gilead.com';McManus, Ayanna (NIH/OD) [E];Wood, Gretchen

(NIH/OD) [E]

Subject: Target Validation Call

### Dear Norbert,

As you know, the Target Validation Consortium recently brought together leading academics and industry representatives to develop detailed research plans in four disease areas. We are enthusiastic that the proposals will help us find more efficient routes to validate drug targets, reversing the current trend of costly late-stage failures.

I am happy to announce that the NIH is pledging significant support for each project across all disease areas. We have committed to funding 50% of the total research costs and have the full support of the Directors of NIMH, NIA, NIDDK, NIAMS, and NIAID.

I would like to briefly discuss this with you early next week; I don't expect the phone call to take more than 10 minutes. Please have your assistant contact Gretchen or Ayanna to schedule a convenient time to chat.

I look forward to hearing from you soon.

Best regards, Francis From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 16 Aug 2013 20:32:57 +0000

To: 'Doug.williams@biogenidec.com'

Cc: 'Bruce.Warren@biogenidec.com';McManus, Ayanna (NIH/OD) [E];Wood,

Gretchen (NIH/OD) [E]

Subject: Target Validation Call

### Dear Doug,

As you know, the Target Validation Consortium recently brought together leading academics and industry representatives to develop detailed research plans in four disease areas. We are enthusiastic that the proposals will help us find more efficient routes to validate drug targets, reversing the current trend of costly late-stage failures.

I am happy to announce that the NIH is pledging significant support for each project across all disease areas. We have committed to funding 50% of the total research costs and have the full support of the Directors of NIMH, NIA, NIDDK, NIAMS, and NIAID.

I would like to briefly discuss this with you early next week; I don't expect the phone call to take more than 10 minutes. Please have your assistant contact Gretchen or Ayanna to schedule a convenient time to chat.

I look forward to hearing from you soon.

Best regards, Francis

Francis S. Collins, M.D., Ph.D. Director, National Institutes of Health

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 16 Aug 2013 20:28:27 +0000

To: 'peter.carberry@us.astellas.com'

Cc: Wood, Gretchen (NIH/OD) [E]; 'Sanja.Kurtagic-Kadunic@astellas.com'; McManus,

Ayanna (NIH/OD) [E]

Subject: Target Validation Call

# Dear Peter,

As you know, the Target Validation Consortium recently brought together leading academics and industry representatives to develop detailed research plans in four disease areas. We are enthusiastic that the proposals will help us find more efficient routes to validate drug targets, reversing the current trend of costly late-stage failures.

I am happy to announce that the NIH is pledging significant support for each project across all disease areas. We have committed to funding 50% of the total research costs and have the full support of the Directors of NIMH, NIA, NIDDK, NIAMS, and NIAID.

I would like to briefly discuss this with you early next week; I don't expect the phone call to take more than 10 minutes. Please have your assistant contact Gretchen or Ayanna to schedule a convenient time to chat.

I look forward to hearing from you soon.

Best regards, Francis

Francis S. Collins, M.D., Ph.D. Director, National Institutes of Health

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 16 Aug 2013 20:43:17 +0000

To: 'mkt@novonordisk.com'

Cc: 'toft@novonordisk.com';McManus, Ayanna (NIH/OD) [E];Wood, Gretchen

(NIH/OD) [E]

Subject: Target Validation Call

Dear Mads,

As you know, the Target Validation Consortium recently brought together leading academics and industry representatives to develop detailed research plans in four disease areas. We are enthusiastic that the proposals will help us find more efficient routes to validate drug targets, reversing the current trend of costly late-stage failures.

I am happy to announce that the NIH is pledging significant support for each project across all disease areas. We have committed to funding 50% of the total research costs and have the full support of the Directors of NIMH, NIA, NIDDK, NIAMS, and NIAID.

I would like to briefly discuss this with you early next week; I don't expect the phone call to take more than 10 minutes. Please have your assistant contact Gretchen or Ayanna to schedule a convenient time to chat.

I look forward to hearing from you soon.

Best regards, Francis 
 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Mon, 5 Aug 2013 20:35:09 +0000

To: chin@phrma.org

**Subject:** Target Validation Consortium

Attachments: TVC - Overview Discussion - 130715 - vFinal.pptx

Hi Bill,

It was great to talk with you today. Attached is the current "pitch deck" that is being used to ascertain company interests in participation in the Target Validation Consortium. This should give you a pretty good idea of the proposed consortium's activities – though there is a lot more to back this up in the white papers that the design teams assembled.

I very much appreciate your willingness to help think about this, and I'll look forward to checking in with you again next week.

Best, Francis

## Target Validation ConsortiumOverview

July 2013

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From:Collins, Francis (NIH/OD) [E]Sent:Fri, 26 Jul 2013 20:49:46 +0000To:Moncef.m.slaoui@gsk.comCc:clare.x.smith@gsk.comSubject:Target Validation ConsortiumAttachments:TVC - Overview Discussion - 130715 - vFinal.pptx

Hi Moncef,

| really enjoyed today's meeting on electroceuticals. | (6) (4) |
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| Your leadership is much appreciated!                |         |
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I would be glad to discuss this further with you if that would be useful. I believe the TVC is an excellent example of the much-needed innovative precompetitive models that you highlighted in your opening remarks this morning.

Best regards,

Francis

## Target Validation ConsortiumOverview

July 2013

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From: Collins, Francis (NIH/OD) [E]

Sent: Tue, 25 Jun 2013 22:18:24 +0000

To: Green, Eric (NIH/NHGRI) [E]

Cc: Tabak, Lawrence (NIH/OD) [E]

Subject: Target Validation Consortium

Hi Eric,

Larry and I were discussing the situation with the TVC just now – and wondering whether one of the FY14 BD2K centers could be focused on building the Knowledge Portal described in the diabetes proposal—with the intent to making it generalizable to many other diseases (as Sz, AD, and RA/lupus now say they want).

(b) (5)

Thoughts?

FC

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Wed, 7 Aug 2013 19:30:49 +0000

To: elias.zerhouni@sanofi.com (b) (6)

Subject: Target Validation Consortium

Attachments: TVC - Overview Discussion - 130715 - vFinal.pptx

Hi Elias,

It was great to speak with you by phone this afternoon. Attached is a ppt deck that outlines the scientific plan for the Target Validation Consortium. It would be great to have Sanofi's participation. I know that Mikael Dolsten will also be speaking with you about this, but I'd be glad to talk further at any time.

Best personal regards, Francis

## Target Validation ConsortiumOverview

July 2013

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Collins, Francis (NIH/OD) [E] From: Sent: Tue, 2 Jul 2013 11:50:25 +0000 To: Wholley, David (FNIH) [T] Cc: Freire, Maria (FNIH) [T]; Wood, Gretchen (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E];McManus, Ayanna (NIH/OD) [E] Subject: this afternoon's meeting Hi David, For this afternoon's meeting, can you bring along a current outline of the governance plan for TVC? Issues that we will need to discuss will include: (b) (5), (b) (4) There will no doubt be more! See you soon.

FC

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Tue, 23 Jul 2013 18:54:18 +0000

To: George, Jill (NIH/OD) [E];Kolberg, Rebecca (NIH/OD) [E];Burklow, John (NIH/OD)

[E]

Subject: TVC "pitch deck"

Attachments: TVC pitch deck 062813.pptx

See attached. (b) (5) (b) (5)

FC

## Target Validation ConsortiumOverview

June 2013

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From: (b) (6)

**Sent:** Fri, 26 Jul 2013 07:44:16 -0400

To: Palisch Chase;Ringel Michael;Cairns-Smith Sarah

Subject: TVC

I'll be calling in from the train this morning-- and it's possible the signal may be erratic.

Sent from my iPhone

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 20 Sep 2013 12:35:38 +0000

To: Wholley, David (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E]

Subject: TVC

HI David and Kathy,

We really need to get plans together for how these three TVC programs are going to be managed – RFPs, review, awards, governance.

I know you two have already been talking, but I need to jump in very soon.

Any chance of a phone call at 3 PM today?

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 24 Oct 2013 19:25:08 +0000

To: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

Subject: TVC call tomorrow AM

Can you get access to a room on the 6 for the 8 AM call tomorrow, so that those of us involved in SMRB can just walk down the hall for the SMRB meeting?

If there's a problem with that plan, Steve Katz has also offered his office for the call.

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 26 Jul 2013 16:30:40 +0000

To: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6)

);Palisch Chase (b) (6)

Subject: TVC materials for Moncef

I just spoke to (b) (5)

Is the pitch deck the best summary to send him?

From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 24 Oct 2013 17:01:27 +0000

To: Palisch Chase;Ringel Michael (b) (6);Cairns-

Smith Sarah (b) (6)

Cc: Wholley, David (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]

**Subject:** TVC meeting tomorrow?

Hi all,

It seems that many of my NIH colleagues don't know we are meeting by phone tomorrow at 8 AM. Can you send out a note to that effect ASAP, even if the materials aren't quite ready yet?

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Mon, 30 Sep 2013 19:43:41 +0000

To: Ringel Michael

Cc: McManus, Ayanna (NIH/OD) [E]

Subject: TVC on Oct. 2

Can you give me a quick call at (b) (6)

Thanks, Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 13 Sep 2013 00:15:10 +0000

 To:
 Hudson, Kathy (NIH/OD) [E]

Subject: TVC

Will you join the TVC call tomorrow AM? And have you and David Wholley met already to talk about post-decision project management, or is that something you're doing later tomorrow?

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 23 Aug 2013 19:37:49 +0000

To: Ringel Michael (b) (6); Cairns-Smith Sarah (b) (6)

;Palisch Chase (b) (6)

Cc: Hudson, Kathy (NIH/OD) [E]

Subject: Two more TVC calls

Hi all,



Have a good weekend, everyone.

Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 6 Dec 2013 19:49:31 +0000

To: Palisch Chase;Ringel Michael;Hodes, Richard (NIH/NIA) [E];Rodgers,

Griffin (NIH/NIDDK) [E]; 'lundberg\_jan@lilly.com'; Insel, Thomas (NIH/NIMH) [E]; Katz,

Stephen I. (NIH/NIAMS) [E];'francis.cuss@bms.com';'richard.lifton@yale.edu';Hudson, Kathy

(NIH/OD) [E]; Wholley, David (FNIH) [T]; Cairns-Smith

Sarah; 'mikael.dolsten@pfizer.com'; Carter, Robert (NIH/NIAMS) [E]

Cc: McManus, Ayanna (NIH/OD) [E];Bronson, Charlette (NIH/NIA)

[E];Melencio, Cheryl (FNIH) [T];edmonds\_pamela\_j@lilly.com;Wilkerson, Anita D. (NIH/NIDDK) [E];debra.zander@bms.com;Poole, Charlene (NIH/NIDDK) [E];Holt, Tracy

(NIH/NIMH) [E]; Meltzer, Sherry (NIH/NIAMS) [E]; Schulke, Hilda (NIH/OD)

[E];elizabeth.cappello@yale.edu;Brawley, David (NIH/NIDDK)

[E];tim.wagner@pfizer.com;Wood, Gretchen (NIH/OD) [E]

Subject: What's in a name?

Hi all,

We've had several discussions over the last month about a new name for TVC. Now I'm in a situation where I'd like to see if we can resolve this. I have a chance to describe the consortium to a VERY highly placed member of the Executive Branch on Monday, and I'd like to use a better name if we can agree on one.

After quite a bit of brainstorming around here, the preferred name that has emerged is "Accelerating Medicines Partnership", or AMP. That has the nice property of being both a noun and a verb (we're AMPing up the development of new medicines).

Another possibility was ATP (conveys the sense of higher energy, at least for the biology wonks), "Accelerating Therapeutics Partnership". But there was a major initiative from NIST a few years ago by this name ("Advanced Technology Program") and that might lead to confusion.

Members of Core Steering Committee, what are your reactions to AMP?

Best, Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 18 Jul 2013 23:33:17 +0000

To: David Altshuler MD, PhD Subject: Worried about TVC

Can I call you this evening? Anytime between now and 10 PM would work for me.

From: Collins, Francis (NIH/OD) [E]
To: Wholley, David (FNIH) [T]

Subject: Re: Andy Plump

**Date:** Monday, March 24, 2014 12:22:38 PM

## Great!

## Sent from my iPhone

> On Mar 24, 2014, at 8:25 AM, "Wholley, David (FNIH) [T]" <dwholley@fnih.org> wrote:

>

- > Just wanted you to know that I spoke with Andy Plump for a second time this morning and confirmed his wholehearted participation as co-chair of the AMP T2D SC. I told him to expect more intense demands on his time between now and mid-summer by the way. Maria Vassileva will be in touch with him on meeting and teleconference dates etc. Thanks
- > David

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Sun, 1 Jun 2014 00:31:28 +0000

To: Dolsten, Mikael Subject: diagnostics

Hi Mikael,

To follow up on the discussion we had about multiplex diagnostics at Hever, I have had conversations with people here at NIH who are engaged on this topic. It might be good to get a dialogue going about this, even in advance of your visit to NIH in July. Is there someone in your immediate staff who has the lead on this issue that I could connect with appropriate NIH experts?

Thanks, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Sun, 1 Jun 2014 18:34:51 +0000

To: Sogaard, Morten

Cc: Dolsten, Mikael; Hudson, Kathy (NIH/OD) [E]

Subject: RE: diagnostics

Hi Morten,

Let me "introduce" you to Dr. Kathy Hudson, the NIH Deputy Director for Science, Outreach, and Policy – she has been working with FDA and CMS on molecular diagnostics, and will be the point person for us on this interesting discussion with pharma.

Regards, Francis Collins

From: Sogaard, Morten [mailto:Morten.Sogaard@pfizer.com]

Sent: Saturday, May 31, 2014 9:36 PM

To: Dolsten, Mikael; Collins, Francis (NIH/OD) [E]

Cc: Sogaard, Morten Subject: RE: diagnostics

Mikael and Francis,

We are currently working to get team members on board for this effort from the Hever members.

## Francis,

It is a pleasure to make your acquaintance. It would be exciting and much appreciated if you could connect us with one or a couple of NIH delegates for this important effort.

Kind regards,

Morten

Morten Sogaard, Ph.D. | Vice President, Head Enterprise Scientific Technology Operations, Worldwide R&D |
Pfizer Inc 235 East 42<sup>nd</sup> Street, Office 235/6/21 | New York, NY 10017 | Phone: 212-733-2446 | Mobile | (b) (6) |
morten.sogaard@pfizer.com Assistant: rosetta.giurdarella@pfizer.com | Phone: 212-573-1268

From: Dolsten, Mikael

**Sent:** Saturday, May 31, 2014 9:12 PM **To:** Collins, Francis (NIH/OD) [E]

Cc: Sogaard, Morten Subject: Re: diagnostics

Francis

Good to hear from you

We have reached out to the HEVER Pharma to get their Dx representatives and hence it was perfect timing to hear from you

|                                                                   | (b) (4), (b) (5) |
|-------------------------------------------------------------------|------------------|
|                                                                   |                  |
|                                                                   |                  |
| I look forward to visiting NIH                                    |                  |
| By the way how is the CTI dialogue going from a NIH perspective ? |                  |
| Best                                                              |                  |
| Mikael                                                            |                  |
| Sent from my iPhone                                               |                  |
| On May 31, 2014, at 20:31, "Collins, Francis (NIH/OD) [E]"        | (b) (6) wrote:   |

To follow up on the discussion we had about multiplex diagnostics at Hever, I have had conversations with people here at NIH who are engaged on this topic. It might be good to get a dialogue going about this, even in advance of your visit to NIH in July. Is there someone in your immediate staff who has the lead on this issue that I could connect with appropriate NIH experts?

Thanks, Francis

Hi Mikael,

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 5 Sep 2014 09:15:01 +0000

To: mikael.dolsten@pfizer.com

Subject: AMP Extended Exec Comm

Hi Mikael,

I hope all is well with you. I wanted to see if there was any way that you might be able to arrange your schedule to join the upcoming AMP Extended Executive Committee meeting, now tentatively planned for October 10 from noon to 1:30 PM EDT. With such a busy group, it's been hard to find a time that works for everyone – but this is the closest we have come in the month of October. FNIH indicates that this was not a good date and time for you, but I'm wondering if there is some way you could swing it.

Alternatively, we may need to seek another date in November, but I'm hoping we can meet sooner than that.

Thanks in advance for any schedule magic you might be able to achieve.

Best, Francis

P.S. Not sure if you are able to join today – but I'm looking forward to the AMP conference call this morning at 8 AM EDT.

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 5 Sep 2014 09:15:48 +0000

To: 'lundberg\_jan@lilly.com' (lundberg\_jan@lilly.com)

Subject: AMP Extended Exec Comm

Hi Jan,

I hope all is well with you. I wanted to see if there was any way that you might be able to arrange your schedule to join the upcoming AMP Extended Executive Committee meeting, now tentatively planned for October 10 from noon to 1:30 PM EDT. With such a busy group, it's been hard to find a time that works for everyone – but this is the closest we have come in the month of October. FNIH indicates that this was not a good date and time for you, but I'm wondering if there is some way you could swing it.

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Best, Francis

P.S. Not sure if you are able to join today – but I'm looking forward to the AMP conference call this morning at 8 AM EDT.

From: Collins, Francis (NIH/OD) [E]
Sent: Mon, 11 Aug 2014 20:29:39 +0000

To: Lifton, Richard Subject: AMP going forward

Hi Rick,

Hope you are having a good summer. I'm just writing to check in about AMP. Progress has been excellent for all three areas – but thoughtful advice from people with experience in both academia and industry will continue to be crucial, to be sure we build on the momentum that has already started. In that regard, I am hopeful that you would be willing to continue the role that you played so helpfully during the development of the plans. I know you are terrifically busy, but would you be willing to continue to serve on the Executive Committee (in fact, officially you never left!). The burden is light – occasional materials to review, a one hour monthly conference call with Dolsten, Lundberg, Cuss, me, and other EC members, and a willingness to take occasional phone calls from me about ideas and challenges. Might you be willing to do this?

Thanks, and best regards, Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Sat, 20 Sep 2014 12:46:20 +0000

To: Wholley, David (FNIH) [T]

Subject: FNIH AMP review process

Hi David,

For the (b) (5)

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 5 Sep 2014 16:13:44 +0000

To: Wholley, David (FNIH) [T]

Cc: Gadbois, Ellen (NIH/OD) [E]

Subject: FW: AMP Extended Exec Comm

Can someone follow up with Ann?

From: Protasiewicz, Ann [mailto:Ann.Protasiewicz@pfizer.com]

Sent: Friday, September 05, 2014 9:59 AM

To: Collins, Francis (NIH/OD) [E]

Subject: RE: AMP Extended Exec Comm

Francis,

Per Mikael's request, I am reaching out to you to follow up on the request for Mikael's availability for 1.5 hours for the next AMP Exec. Comm. meeting. Is there someone in your office that I should work with on this?

## Ann

Ann Martin Protasiewicz
Executive Assistant to
Mikael Dolsten, President
Worldwide Research and Development
Pfizer Inc.
235 East 42<sup>nd</sup> Street, Floor 22
New York, NY 10017
212-733-5859 (Office)
(b) (6) (Mobile)

E-Mail - ann.protasiewicz@pfizer.com

From: Dolsten, Mikael

Sent: Friday, September 5, 2014 8:35 AM

To: Collins, Francis (NIH/OD) [E]

Cc: Protasiewicz, Ann

Subject: Re: AMP Extended Exec Comm

October 9 , 330 pm to 5 pm works too! Or 4-530 pm that day

Sent from my iPhone

On Sep 5, 2014, at 7:12, "Collins, Francis (NIH/OD) [E]" (b) (6) wrote:

Great, thanks! Talk to you shortly...

**From:** Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Friday, September 05, 2014 7:11 AM

To: Collins, Francis (NIH/OD) [E]

Subject: Re: AMP Extended Exec Comm

Francis

Thanks for the note

I will check my calendar again but we had a few difficult to move corporate meetings

I can provide several other suggestions the next few weeks

I was planning to call in at 8 am

Sent from my iPhone

On Sep 5, 2014, at 5:15, "Collins, Francis (NIH/OD) [E]" (b) (6) wrote:

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Alternatively, we may need to seek another date in November, but I'm hoping we can meet sooner than that.

Thanks in advance for any schedule magic you might be able to achieve.

Best, Francis

P.S. Not sure if you are able to join today – but I'm looking forward to the AMP conference call this morning at 8 AM EDT.

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 5 Sep 2014 13:21:14 +0000

To: Wholley, David (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]

Subject: FW: AMP Extended Exec Comm

From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Friday, September 05, 2014 8:35 AM

To: Collins, Francis (NIH/OD) [E]

Cc: Protasiewicz, Ann

Subject: Re: AMP Extended Exec Comm

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Thanks in advance for any schedule magic you might be able to achieve.

Best, Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 5 Sep 2014 12:00:58 +0000

To: Wholley, David (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]

**Subject:** FW: AMP Extended Exec Comm

Possible?

From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Friday, September 05, 2014 7:47 AM

To: Collins, Francis (NIH/OD) [E]

Cc: Protasiewicz, Ann

Subject: Re: AMP Extended Exec Comm

Francis

I can actually do our traditional 8-930 am time on October 10, would that work?

Sent from my iPhone

On Sep 5, 2014, at 7:12, "Collins, Francis (NIH/OD) [E]" (b) (6) wrote:

Great, thanks! Talk to you shortly...

**From:** Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Friday, September 05, 2014 7:11 AM

To: Collins, Francis (NIH/OD) [E]

Subject: Re: AMP Extended Exec Comm

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Thanks in advance for any schedule magic you might be able to achieve.

Best, Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 5 Sep 2014 11:25:27 +0000

To: Gadbois, Ellen (NIH/OD) [E]

Subject: FW: AMP Extended Exec Comm

From: Collins, Francis (NIH/OD) [E]

Sent: Friday, September 05, 2014 7:13 AM

To: 'Dolsten, Mikael'

Subject: RE: AMP Extended Exec Comm

Great, thanks! Talk to you shortly...

From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Friday, September 05, 2014 7:11 AM

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Best, Francis

P.S. Not sure if you are able to join today – but I'm looking forward to the AMP conference call this

morning at 8 AM EDT.

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 5 Sep 2014 11:12:47 +0000

To: Wholley, David (FNIH) [T]

Subject: FW: AMP Extended Exec Comm

**From:** Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Friday, September 05, 2014 7:11 AM

To: Collins, Francis (NIH/OD) [E]

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Best, Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 5 Sep 2014 18:03:10 +0000

To: Wholley, David (FNIH) [T]

Subject: FW: AMP Extended Exec Comm

From: Jan Lundberg [mailto:lundberg\_jan@lilly.com]

Sent: Friday, September 05, 2014 1:01 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Pamela J Edmonds

Subject: Re: AMP Extended Exec Comm

#### Francis.

Unfortunately I will be in 60 on October 10 on a since long planned vacation so I would prefer November as meeting date. Alternatively I can give my comments in writing before the meeting which I understand is not optimal,

Best Jan

Sent from my iPhone

On Sep 5, 2014, at 10:16 AM, "Collins, Francis (NIH/OD) [E]" (b) (6) wrote:

Hi Jan,

I hope all is well with you. I wanted to see if there was any way that you might be able to arrange your schedule to join the upcoming AMP Extended Executive Committee meeting, now tentatively planned for October 10 from noon to 1:30 PM EDT. With such a busy group, it's been hard to find a time that works for everyone – but this is the closest we have come in the month of October. FNIH indicates that this was not a good date and time for you, but I'm wondering if there is some way you could swing it.

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 Fri, 5 Sep 2014 11:12:39 +0000

To: Dolsten, Mikael

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To: Collins, Francis (NIH/OD) [E]

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Thanks in advance for any schedule magic you might be able to achieve.

Best, Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Mon, 22 Sep 2014 20:46:14 +0000

To: Wholley, David (FNIH) [T]
Subject: RE: FNIH AMP review process

Thanks, David. (b) (5)

FC

From: Wholley, David (FNIH) [T]

Sent: Monday, September 22, 2014 11:06 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: FNIH AMP review process

Francis,

If you are referring to the RFA(s) out of NIDDK, those are managed through the usual NIH grants review process. I am still waiting to hear if and how additional NIH funds may be directed toward AMP T2D, but assume you are outside those discussions given the potential for conflicts.

The process of

(b) (5)

(b) (5)

(b)(5)

(b) (5) Therefore, I think you'd be OK. Let me know if there is any part of this process with which you are uncomfortable.

Thanks, David

From: <Collins>, "Francis [E] (NIH/OD)" (b) (6)

Date: Saturday, September 20, 2014 at 8:46 AM

To: David Wholley < <a href="mailto:dwholley@fnih.org">dwholley@fnih.org</a> Subject: FNIH AMP review process

Hi David,

For the (b) (5)

FC

From: Collins, Francis (NIH/OD) [E]

To: <u>Dolsten, Mikael</u>
Subject: diagnostics

**Date:** Saturday, May 31, 2014 8:31:00 PM

Hi Mikael,

To follow up on the discussion we had about multiplex diagnostics at Hever, I have had conversations with people here at NIH who are engaged on this topic. It might be good to get a dialogue going about this, even in advance of your visit to NIH in July. Is there someone in your immediate staff who has the lead on this issue that I could connect with appropriate NIH experts?

Thanks, Francis

From: Collins, Francis (NIH/OD) [E]

To: Sogaard, Morten

Cc: Dolsten, Mikael; Hudson, Kathy (NIH/OD) [E]

Subject: RE: diagnostics

**Date:** Sunday, June 1, 2014 2:34:00 PM

#### Hi Morten,

Let me "introduce" you to Dr. Kathy Hudson, the NIH Deputy Director for Science, Outreach, and Policy – she has been working with FDA and CMS on molecular diagnostics, and will be the point person for us on this interesting discussion with pharma.

## Regards, Francis Collins

From: Sogaard, Morten [mailto:Morten.Sogaard@pfizer.com]

Sent: Saturday, May 31, 2014 9:36 PM

To: Dolsten, Mikael; Collins, Francis (NIH/OD) [E]

**Cc:** Sogaard, Morten **Subject:** RE: diagnostics

## Mikael and Francis,

We are currently working to get team members on board for this effort from the Hever members.

### Francis,

It is a pleasure to make your acquaintance. It would be exciting and much appreciated if you could connect us with one or a couple of NIH delegates for this important effort.

## Kind regards,

Morten

Morten Sogaard, Ph.D. | Vice President, Head Enterprise Scientific Technology Operations, Worldwide R&D |

Pfizer Inc 235 East 42<sup>nd</sup> Street, Office 235/6/21 | New York, NY 10017 | Phone: 212-733-2446 | Mobile (b) (6)

morten.sogaard@pfizer.com Assistant: rosetta.giurdanella@pfizer.com | Phone: 212-573-1268

From: Dolsten, Mikael

**Sent:** Saturday, May 31, 2014 9:12 PM **To:** Collins, Francis (NIH/OD) [E]

**Cc:** Sogaard, Morten **Subject:** Re: diagnostics

## Francis

Good to hear from you

We have reached out to the HEVER Pharma to get their Dx representatives and hence it was perfect timing to hear from you

I cc Morten Sogaard (VP Pfizer Enterprisewide Scientific Technology Operations) who will lead the efforts of our diagnostic NGS/WGS HEVER team . Great if you can connect Morten to the NIH key person(s)

I look forward to visiting NIH

By the way how is the CTI dialogue going from a NIH perspective?

Best

Mikael

Sent from my iPhone

On May 31, 2014, at 20:31, "Collins, Francis (NIH/OD) [E]" (b) (6) wrote:

Hi Mikael,

To follow up on the discussion we had about multiplex diagnostics at Hever, I have had conversations with people here at NIH who are engaged on this topic. It might be good to get a dialogue going about this, even in advance of your visit to NIH in July. Is there someone in your immediate staff who has the lead on this issue that I could connect with appropriate NIH experts?

Thanks, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 30 Oct 2014 18:42:53 +0000

To: Allan Jones

Cc: Wholley, David (FNIH) [T];Hudson, Kathy (NIH/OD) [E]

Subject: Accelerating Medicines Partnership and AIBS

Hi Allan,

I imagine you have heard about the unique partnership between NIH and several pharmaceutical companies to try to speed up the process of identifying new drug targets and biomarkers – called AMP, for the Accelerating Medicines Partnership. See http://www.nih.gov/science/amp/index.htm.

The three areas of current focus are Alzheimer's disease, type 2 diabetes, and rheumatoid arthritis/lupus.

For Alzheimer's disease, four companies have signed on, and there are two major goals: 1) ensure that all clinical trials run by NIH or pharma utilize the same set of biomarkers, including tau imaging; 2) a systems biology approach to understanding the most important differences between normal and Alzheimer brains, using a wide variety of experimental –omics approaches and data analysis.

The program is just getting started, but there is much excitement about its promise. Though pharma is paying half of the costs (total is \$130M for the Alzheimer project over 5 years), access to data is open to all researchers (whether or not they are part of AMP). We could go faster if we were not limited in resources.

A number of non-profits have also joined this effort. It occurred to me that this might be of interest to Paul Allen, and so I'm reaching out to see if that would be worth pursuing. Would it be useful for David Wholley, who manages AMP for the Foundation for NIH, to provide you with more details?

Thanks for considering.

Best, Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 19 Dec 2014 13:33:49 +0000

 To:
 Smith, Philip (NIH/NIDDK) [E]

Cc: Wholley, David (FNIH) [T]; Wood, Gretchen (NIH/OD) [E]

Subject: AMP T2D SC co-chair

If you can, call me right after this EC call. (b) (6)

From: Collins, Francis (NIH/OD) [E]

Sent: Thu, 30 Oct 2014 18:48:05 +0000

To: Andrew.plump@sanofi.com

Cc: Wholley, David (FNIH) [T]

Subject: AMP

Hey there Andy,

I spoke this afternoon with David Wholley about progress on the AMP collaboration. He assured me that things are going quite well with all three areas of focus — (b) (5)

I just thought I'd check in with you about this. I am personally very hopeful that you can continue in this role — as your expertise is exactly what's needed to keep the momentum going in this exciting area. Can you figure out a way to make this work?

(b)(5)

Best, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 20 Nov 2014 18:03:55 +0000

To: Dolsten, Mikael

Cc: Wholley, David (FNIH) [T]

Subject: Dividing up the introduction for AMP tomorrow?

Attachments: AMP Ext EC 11-21-2014 slides\_19 Nov-FINAL.pptx

HI Mikael,

I am looking forward to the AMP Extended Steering Committee call tomorrow afternoon. As you can see from the agenda (slide 3 in the attached file), you and I are doing the first ten minutes or so, reminding people of the origins of AMP and setting the stage for the specific project discussions.

How about you do slides 4-7 (and 7 won't require a lot of time, since we will be going over the details of the projects in the main body of the call), and I do 8-11? Or if you'd prefer, we can flip that around - I'd be fine with either option.

Just let me and David know so we can orchestrate accordingly.

All the best, Francis



# Today's meeting participants

## Industry participants

## Government participants

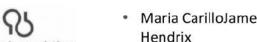
## Non-profit participants



Michael DeckerJim Sullivar



Francis Collins Ellen





**Doug Williams** 





alzheimer's association

Howard Fillit



Francis Cuss



Neil BuckholtzRichard Hodes



David Shuey



Lon Cardon





National Institute of

Diabetes and Digestive

and Kidney Diseases

Bob CarterStephen Katz



Marlon Pragnell



Leslie Hanrahan



Rheumatology Research Foundation

FNIH

Bill Chin

David Karp



Rupert Vessey

Michael Hutton



Mikael DolstenMarty Hodge



Andrew **PlumpElias** Zerhouni



Janet Woodcock

RodgersPhilip Smitti

Griffin



Myanting Treatment Finding Cores

**Facilitators** 







Jonathan Zalevsky NIH - 000387















## AMP Governance and Membership

### **Extended Executive Committee**

Bill Chin, PhRMABill HaiDoug Williams, Biogen-J&JJim Sullivan, IdecJanet Woodcock, AbbViePatrick Vallance, FDATachi Yamada, GSKRupert Vessey, TakedaElias Zerhouni, Merck Sanofi Core Executive Committee
Co-chairsFrancis Mikael Dolsten, Pfizer
Collins, NIH
MembersFrancis Cuss<sub>Rick Lifton</sub>, YaleJan Lundberg,
BMSRichard Hodes, LillyGriffin Rodgers,
NIAKathy Hudson, NIDDKSharon Terry, Genetic
NIHSteve Katz, NIAMSAlliance

## Executive and Steering Committee Support

 David Wholley, FNIHRosa Canet-Aviles, FNIHMaria Vassileva, FNIHSteve Hoffmann, FNIHSanya Fanous Whitaker, FNIH

## Alzheimer's disease Steering Committee

Co-chairsMike Decker, AbbVieNeil Buckholtz, NIAEC LiaisonRichard Hodes, NIAMembersMaria Carrillo, ALZHoward Fillit, ADDFXiaoming Guan, GSKTim Harris, Biogen IdecWalter Koroshetz, NINDSMark Mintun, Lilly Pat Walicke, NINDSBilly Dunn, FDA

## Type 2 DiabetesSteering Committee

Co-chairsAndy Plump, SanofiPhil Smith, I

## RA, SLE Steering Committee

Co-chairsMarty Hodge, PfizerBob
Carter, NIAMSEC LiaisonSteve Katz,
NIAMSMembersChristopher Arendt,
SanofiJeff Browning,
ALR/LRICarolyn Cuff, AbbVieMarc
Levesque, AbbVieAndrey Loboda,
MerckSatwant Narula, BMSLisa
Olson, AbbVieDan Rotrosen,
NIAIDDavid Shuey, Arthritis
FoundationJonathan Zalevsky,
TakedaDennis Zaller, Merck

NIH - 000395



# Accelerating Medicines PartnershipAlzheimer's Disease









# AMP AD Steering Committee and Additional Stakeholder Representatives

|                             | Name                             | Affiliation             |  |
|-----------------------------|----------------------------------|-------------------------|--|
| Co Chaire                   | Neil Buckholtz                   | NIH/NIA                 |  |
| Co-Chairs                   | Mike Decker                      | Abbvie                  |  |
|                             | Xiaoming Guan                    | GSK                     |  |
| Industry                    | Tim Harris                       | Biogen Idec             |  |
|                             | Mark Mintun                      | Lilly                   |  |
|                             | Maria Carrillo                   | Alzheimer's Association |  |
|                             | Billy Dunn                       | FDA                     |  |
| Academia,                   | Howard Fillit                    | ADDF                    |  |
| Government, &<br>Non-profit | Walter Koroshetz and Pat Walicke | NIH/NINDS               |  |
|                             | Suzana Petanceska                | NIH/NIA                 |  |
|                             | Laurie Ryan                      | NIH/NIA                 |  |

EC LiaisonRichard Hodes, NIH/NIA

(\*) Other contributing Organizations: Geoffrey Beene Foundation and USAgainstAlzheimer's























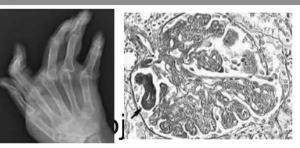
### **Accelerating Medicines PartnershipRA/SLE**





#### **Progress Update Outline**

 Background and Goals Funders and Program ManagementSteering Committee Project St



TimelineSummary of NIH Grant AwardsProject ProgressNext Steps and Future Challenges





### AMP RA/SLE Participation

Industry members













Government members





Non-profit members















NIH - 000415





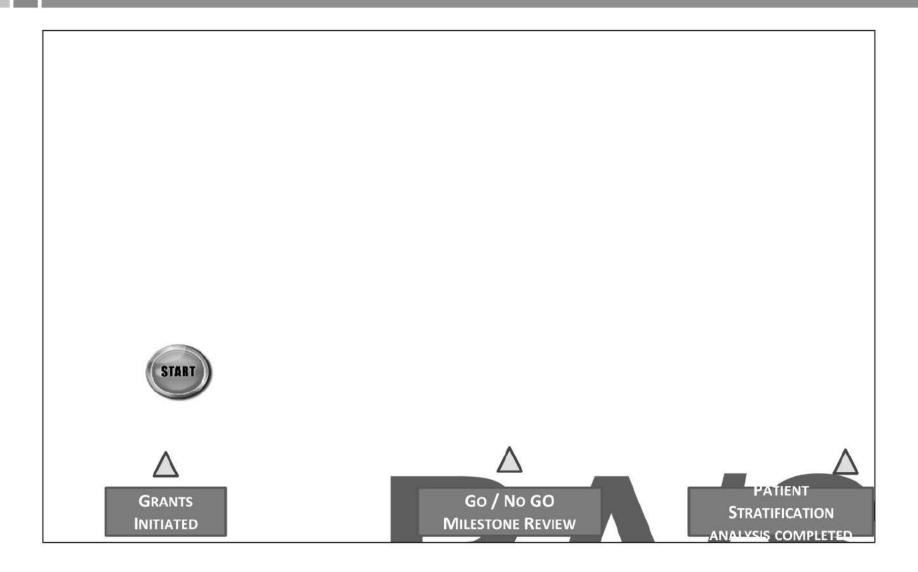








## Project Timeline



NIH - 000422























NIH - 000





# Project Background: Steering Committee and Additional Stakeholder Representatives

| Beena Akolkar, NIDDK/NIH   | Jeffrey Pfefferkorn, Pfizer         | Maria Vassileva, FNIH         |
|----------------------------|-------------------------------------|-------------------------------|
| Olivier Blondel, NIDDK/NIH | Andrew Plump , Sanofi, co -chair    | Clarence Wang, Sanofi-Genzyme |
| Martin Brenner , Merck     | Dan Rader , UPenn                   | Tao Wei, Lilly                |
| Julia Brosnan, Pfizer      | Dermot Reilly, Merck                | Sanya Fanous Whitaker, FNIH   |
| Eric Fauman, Pfizer        | Hartmut Ruetten, Sanofi             |                               |
| Joe Hedrick , Janssen      | Philip Smith,<br>NIH/NIDDK,co-chair |                               |
| Tony Parrado, Janssen      | Melissa Thomas, Lilly               |                               |

























## Appendices





















 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 30 Oct 2014 18:43:13 +0000

 To:
 Gadbois, Ellen (NIH/OD) [E]

Subject: FW: Accelerating Medicines Partnership and AIBS

Meant to cc you..

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, October 30, 2014 2:43 PM

To: 'Allan Jones'

**Cc:** Wholley, David (FNIH) [T]; Hudson, Kathy (NIH/OD) [E] **Subject:** Accelerating Medicines Partnership and AIBS

Hi Allan,

I imagine you have heard about the unique partnership between NIH and several pharmaceutical companies to try to speed up the process of identifying new drug targets and biomarkers – called AMP, for the Accelerating Medicines Partnership. See <a href="http://www.nih.gov/science/amp/index.htm">http://www.nih.gov/science/amp/index.htm</a>.

The three areas of current focus are Alzheimer's disease, type 2 diabetes, and rheumatoid arthritis/lupus.

For Alzheimer's disease, four companies have signed on, and there are two major goals: 1) ensure that all clinical trials run by NIH or pharma utilize the same set of biomarkers, including tau imaging; 2) a systems biology approach to understanding the most important differences between normal and Alzheimer brains, using a wide variety of experimental –omics approaches and data analysis.

The program is just getting started, but there is much excitement about its promise. Though pharma is paying half of the costs (total is \$130M for the Alzheimer project over 5 years), access to data is open to all researchers (whether or not they are part of AMP). We could go faster if we were not limited in resources.

A number of non-profits have also joined this effort. It occurred to me that this might be of interest to Paul Allen, and so I'm reaching out to see if that would be worth pursuing. Would it be useful for David Wholley, who manages AMP for the Foundation for NIH, to provide you with more details?

Thanks for considering.

Best, Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 31 Oct 2014 02:00:39 +0000

To: Wholley, David (FNIH) [T]

Cc: Hudson, Kathy (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]

Subject: FW: Accelerating Medicines Partnership and AIBS

HI David.

OK, (b) (5)

FC

----Original Message----

From: Allan Jones [mailto:AllanJ@alleninstitute.org]

Sent: Thursday, October 30, 2014 7:01 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Wholley, David (FNIH) [T]; Hudson, Kathy (NIH/OD) [E] Subject: RE: Accelerating Medicines Partnership and AIBS

Dear Francis,

Would love to hear more! Please send details. Hope all is well with you,

Allan

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Thursday, October 30, 2014 11:42 AM

To: Allan Jones

Cc: Wholley, David (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]

Subject: Accelerating Medicines Partnership and AIBS

Hi Allan,

I imagine you have heard about the unique partnership between NIH and several pharmaceutical companies to try to speed up the process of identifying new drug targets and biomarkers – called AMP, for the Accelerating Medicines Partnership. See http://www.nih.gov/science/amp/index.htm.

The three areas of current focus are Alzheimer's disease, type 2 diabetes, and rheumatoid arthritis/lupus.

For Alzheimer's disease, four companies have signed on, and there are two major goals: 1) ensure that all clinical trials run by NIH or pharma utilize the same set of biomarkers, including tau imaging; 2) a systems biology approach to understanding the most important differences between normal and Alzheimer brains, using a wide variety of experimental –omics approaches and data analysis.

The program is just getting started, but there is much excitement about its promise. Though pharma is paying half of the costs (total is \$130M for the Alzheimer project over 5 years), access to data is open to all researchers (whether or not they are part of AMP). We could go faster if we were not limited in resources.

A number of non-profits have also joined this effort. It occurred to me that this might be of interest to Paul Allen, and so I'm reaching out to see if that would be worth pursuing. Would it be useful for David Wholley, who manages AMP for the Foundation for NIH, to provide you with more details?

Thanks for considering.

Best, Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 31 Oct 2014 10:15:20 +0000

To: Wholley, David (FNIH) [T]

Subject: FW: AMP

(b) (5)

FC

**From:** Andrew.Plump@sanofi.com [mailto:Andrew.Plump@sanofi.com]

Sent: Thursday, October 30, 2014 8:36 PM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Wholley, David (FNIH) [T]

Subject: RE: AMP

Hi Francis,

Thanks you for reaching out and in your characteristic energetic and charismatic manner, encouraging me to say on in this role!

As you know, I believe deeply in what you've put together with AMP and am committed to supporting it. My concern is whether I am able to engage sufficiently to add the necessary level of value. As I discussed briefly with David, I don't want to take up a spot on this important effort and block someone else from stepping in, who might be more engaged and add more direct value. I sense that my sponsorship and intermittent guidance has been helpful to the team, but not sure whether this is sufficient.

I had been planning to reach out to you directly to discuss, but sensitive to your time, I have decided to first discuss this with Phil Smith and see what he thinks.

I don't see relief in my schedule for the coming weeks, particularly now with Chris having left Sanofi, coupled with our budget review cycle coming to a close, but I am eternally optimistic given the priority I place on this that I will be able to work my way back into the mix.

My suggestion is that we stay as is for now. I will find time in the coming weeks to discuss with Phil. Then, perhaps you and I can talk about the best way to handle.

Thanks, Andy

From: Collins, Francis (NIH/OD) [E] [mailto (b) (6)

Sent: Thursday, October 30, 2014 7:48 PM

**To:** Plump, Andrew R&D/FR **Cc:** Wholley, David (FNIH) [T]

Subject: AMP

Hey there Andy,

I spoke this afternoon with David Wholley about progress on the AMP collaboration. He assured me that things are going quite well with all three areas of focus – but mentioned that you were struggling a bit about whether you still had the time to serve as a Steering Committee co-chair for the T2D project.

I just thought I'd check in with you about this. I am personally very hopeful that you can continue in this role – as your expertise is exactly what's needed to keep the momentum going in this exciting area. Can you figure out a way to make this work?

I'm sorry to pose this question to you at a time where no doubt there is some tumult at Sanofi – but I'd appreciate a sense from you about whether this can still work. Personally I really hope so!!

Best, Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Sun, 21 Dec 2014 19:54:17 +0000

To: Wholley, David (FNIH) [T]

Subject: FW: AMP

Hi David,

See a helpful note from Francis Cuss below.

(b)(5)

Any other thoughts on this message, before I respond back to Francis?

Best, FC

From: Cuss, Francis [mailto:francis.cuss@bms.com]

**Sent:** Saturday, December 20, 2014 7:17 AM **To:** Collins, Francis (NIH/OD) [E]

Subject: AMP

Dear Francis,

(b) (4)

On another matter mentioned yesterday, I wanted to re-emphasize how important it is for us to find a way to manage the content and maintain interest during these broadly attended and important communication telecoms to the broader AMP leadership. Managing this sort of meeting effectively has been a particular issue for us in BMS also, so I'm sympathetic to the challenge, and making it better is a particular interest of mine. As a result of my experience in Pharma I'm also very much aware at how easy it is to lose the engagement of the audience if the presentations drag on, the agenda gets telescoped and the questions don't get answered. The watch out for us was that when less than optimal meetings occur regularly, busy, time-disciplined people tend to deprioritize subsequent meetings and not attend. I don't think there is a "magic bullet" solution for this, and many of the suggestion offered by Bob and others can be effective if properly executed.

To summarize what has transformed our meetings are firstly strong norms around everyone getting the meeting content from the pre-reads beforehand; secondly commissioning the leaders of the discussions not to provide content/information on what everyone already agrees on, but to indentify the issues, provide options and solicit opinions/questions and thirdly to have the timing of the meeting agenda rigorously observed (i.e. everyones accountable for the time they use). Applying these simple rules in BMS has resulted in great improvements in the engagement of our meeting participants, in the speed of

our decision-making and about a 50% reduction in the time we spend in meetings. It has specifically enhanced our ability to discuss and make important decisions on highly complex scientific and medical issues and make them accessible to a multi-disciplinary set of attendees (i.e. not just the experts in an area).

I know it all sounds miraculous, but I can't say it's been easy to achieve, because there is a significant adjustment cost for many people and a new set of norms has to be observed: namely that these sort of meetings take a lot of preparation both by the topic leaders and participants, they are not the right forum for lecturing, and that if you're not on topic you're actually irrelevant and wasting the time of everyone. One of the measures of a this sort of change in meeting culture is that meetings running this way tend to end early, because the agendas are more focused and only the issues get discussed. My impression is that the AMP monthly meetings are a model of this, and we did indeed finish early yesterday!

Let me finish by congratulating you on the progress AMP has made this year. I think the success to date reflects the importance of clear leadership and focused shared objectives in the precompetitive space.

With best wishes to you and your family for the Holidays and 2015

Francis

This message (including any attachments) may contain confidential, proprietary, privileged and/or private information. The information is intended to be for the use of the individual or entity designated above. If you are not the intended recipient of this message, please notify the sender immediately, and delete the message and any attachments. Any disclosure, reproduction, distribution or other use of this message or any attachments by an individual or entity other than the intended recipient is prohibited.

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Wed, 17 Dec 2014 21:27:24 +0000

To: Wholley, David (FNIH) [T];Andrew.Plump@sanofi.com

Cc: Smith, Philip (NIH/NIDDK) [E]

Subject: RE: AMP - Diabetes

Hi Andy,

Wow, let me add my congratulations to David's! This sounds like a terrific opportunity, and we will be glad to have good friend at Takeda.

I'll consult with Phil about a possible replacement co-chair.

Quite a week of big changes for you diabetes leaders – first Altshuler, now you!

Francis

From: Wholley, David (FNIH) [T]

Sent: Wednesday, December 17, 2014 2:12 PM

**To:** Andrew.Plump@sanofi.com; Collins, Francis (NIH/OD) [E]

**Cc:** Smith, Philip (NIH/NIDDK) [E] **Subject:** RE: AMP - Diabetes

Andy-

Congratulations—it's a big job as I'm sure you know and a terrific move. I hope it also enables you to

(b) (6)

As you may know, Takeda is already an important partner for AMP in the RA/lupus effort. Please let us know here anything we can do to support you in AMP and of course other partnership efforts that support NIH as you move into your new role.

Best regards,

David

**From:** Andrew.Plump@sanofi.com [mailto:Andrew.Plump@sanofi.com]

Sent: Wednesday, December 17, 2014 1:27 PM

To: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]

Cc: Smith, Philip (NIH/NIDDK) [E]

Subject: AMP - Diabetes

Hi Francis and David,

I hope you are both well and getting ready to take some down time over the holidays.

Wanted to give you a heads up on an announcement coming out tomorrow. I have accepted a position as R&D Head at Takeda, succeeding Tachi Yamada, who will retire in 2015. The position will be based in the States. It's very exciting and an opportunity to continue to drive the mindset you have established in AMP deep into pharma.

My intent had been to wean myself off of the diabetes sub-team and to work with Phil to find a replacement, as I've not been able to pay as much attention to the role as is necessary, though I have been and continue to be an ardent sponsor. This new position will accelerate the need to find someone. Phil and I had discussed approaching the partnering companies to find a senior scientist to take over for me as the industry co-chair. We do not have the right successor currently on the committee

I would like to help with this transition, so very much look forward to your guidance.

This is still confidential as the official word is coming tomorrow, but wanted to give you a heads-up.

Thanks, Andy From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 6 Nov 2014 22:48:39 +0000

To: Pelis, Kim (NIH/OD) [E]

Cc: Kolberg, Rebecca (NIH/OD) [E];George, Jill (NIH/OD) [E];Green, Eric (NIH/NHGRI)

[E]

Subject: RE: AMP - draft outline

Attachments: AMP\_keynote outline draft fsc.docx

Hi Kim,

See attached. I'm ccing Eric Green so he can see where this is going...

FC

From: Pelis, Kim (NIH/OD) [E]

Sent: Thursday, November 06, 2014 4:40 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Kolberg, Rebecca (NIH/OD) [E]; George, Jill (NIH/OD) [E]

Subject: ASHG - draft outline

Hi Dr. Collins,

We hear your GSA talk received rave reviews! Now, on to AMP....

Attached is a rough outline of the topics you mentioned for your Past/Present/Future/Hope sections of the talk. We'll modify as you direct.

Thanks!

Kim

Kim Pelis, PhD NIH/OCPL Bethesda, MD (b) (6)







 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 7 Nov 2014 14:57:36 +0000

To: Pelis, Kim (NIH/OD) [E]

Cc: Kolberg, Rebecca (NIH/OD) [E];George, Jill (NIH/OD) [E]

Subject: RE: AMP - draft outline

Fine to share this outline with Steph, Janet, and Cathy.

From: Pelis, Kim (NIH/OD) [E]

Sent: Friday, November 07, 2014 7:27 AM

To: Collins, Francis (NIH/OD) [E]

Cc: Kolberg, Rebecca (NIH/OD) [E]; George, Jill (NIH/OD) [E]

Subject: RE: AMP - draft outline

Good morning, Dr. Collins,

Two outline-related items. First, yes, that is the official abstract. You approved it way back in early July.

Second, Steph asked that we share a draft of this talk with her, Janet Lambert, and Cathy Fomous, when one was ready. Shall I send this outline, or would you prefer me to wait until later Monday and send them a draft slide set?

Many thanks, Kim

Kim Pelis, PhD NIH/OCPL Bethesda, MD

(b) (5)



From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, November 06, 2014 5:49 PM

To: Pelis, Kim (NIH/OD) [E]

Cc: Kolberg, Rebecca (NIH/OD) [E]; George, Jill (NIH/OD) [E]; Green, Eric (NIH/NHGRI) [E]

Subject: RE: AMP - draft outline

Hi Kim,

See attached. I'm ccing Eric Green so he can see where this is going...

FC

From: Pelis, Kim (NIH/OD) [E]

Sent: Thursday, November 06, 2014 4:40 PM

To: Collins, Francis (NIH/OD) [E]

**Cc:** Kolberg, Rebecca (NIH/OD) [E]; George, Jill (NIH/OD) [E] **Subject:** ASHG - draft outline

Hi Dr. Collins,

We hear your GSA talk received rave reviews! Now, on to AMP....

Attached is a rough outline of the topics you mentioned for your Past/Present/Future/Hope sections of the talk. We'll modify as you direct.

Thanks! Kim

Kim Pelis, PhD NIH/OCPL Bethesda, MD (b) (5)



 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Wed, 12 Nov 2014 00:56:20 +0000

To: Pelis, Kim (NIH/OD) [E]

Cc: George, Jill (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna

(NIH/OD) [E]

Subject: RE: AMP - draft slides

Attachments: AssocMolecPath\_111214.pptx

Here's the final set. Many thanks!

FC

From: Pelis, Kim (NIH/OD) [E]

Sent: Monday, November 10, 2014 9:05 PM

To: Collins, Francis (NIH/OD) [E]

Cc: George, Jill (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]

Subject: AMP - draft slides

Hi Dr. Collins,

Attached is your draft AMP presentation,

(b)(5)

The slide bullet was adjusted accordingly.

Have a great holiday!

Best, Kim

Kim Pelis, Ph.D. NIH/OCPL

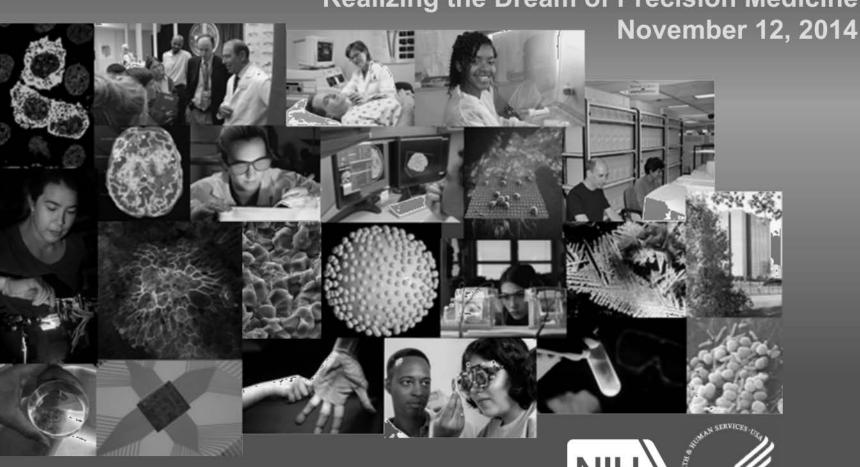
(b) (6)

NIH ... Turning Discovery Into Health®

## Genomics and Medicine: Past, Present, and Future Francis S. Collins, M.D., Ph.D.

**Director, National Institutes of Health** 

Association for Molecular Pathology 2014 Annual Meeting: Realizing the Dream of Precision Medicine





Congratulations, Prof. Uta Francke!

## **Past**

The Genome Project and human health

The FASEB Journal

FRANCIS S. COLLINS

Howard Hughes Medical Institute, Ann Arbor, MI 48109, USA

Vol. 5 January 1991

DESPITE THE IMPRESSIVE ADVANCES IN Western medical care over the past half century, particularly in the management of infectious diseases, medicine remains to a large extent a descriptive and rather empirical discipline. Our knowledge of the basic biology of disease processes, and of the genetic predisposition that contributes in a significant way to most disorders, remains woefully inadequate. Progress in understanding many disorders has been slowed by a "catch 22": it is not possible to fully understand the biology without identifying the genes involved, and it often is not possible to identify the genes without detailed knowledge of the biology.

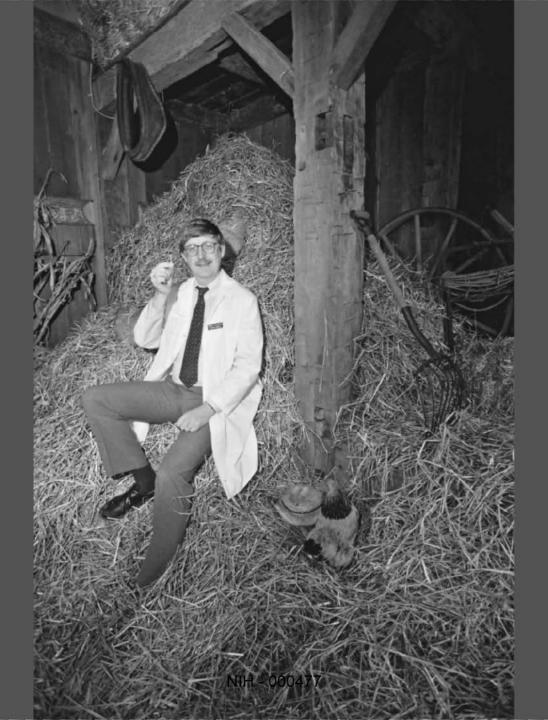
The positional cloning approach, whereby a gene is identified by its map position without making assumptions about the structure or function of its protein product, has provided a powerful alternative to this dilemma. Using this approach, several genes responsible for common inherited disorders, such as cystic fibrosis (CF), Duchenne muscular dystrophy, and neurofibromatosis (NFI) have been described identified.

heimer's disease, the problem becomes more difficult. The necessity of mapping multiple contributing loci simultaneously will require more sophisticated analysis, and the genetic localization will be much more blurred. The gene of interest, even after pushing genetic analysis to the limit, may well be no more precisely located than an interval of 10-20 million base pairs. Without a detailed physical map of the region, including the localization of coding regions, such problems will be almost insurmountable.

"The Genome Project . . . will yield a harvest of information that will drive the research enterprise for at least the next 100 years."

# Cystic Fibrosis The hunt for the causative gene

Cystic fibrosis (CF): Most common, fatal genetic disease in Northern Europeans, affecting 70,000 people worldwide1938: CF recognized as a disease; classic, autosomal recessive inheritance — so the gene must be somewhere1985: Mapped to chromosome 7q by family linkage studies1988: Fine mapping narrows location to ~2 M base pairs between MET and marker J3.11, but...No cytogenetic abnormalitiesNo large deletions



# Cystic Fibrosis Early Discoveries – and Issues

 1989: Discovery of CF gene (CFTR)~90% of patients have DF508-CFTR mutation4–5% have G551D-CFTR mutation1990-92: Determining screening
 recommendations



Am. J. Hum. Genet. 51:1443

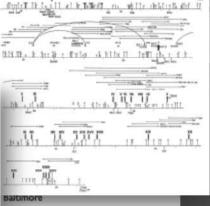
Statement of Cystic Fibrosis



Cystic Fibrosis

#### Identification of the Cystic Fibrosis Gene: Chromosome Walking and Jumping

JOHANNA M. ROMMENS, MICHAEL C. IANNUZZI, BAT-SHEVA KEREM, MITCHELL L. DRUMM, GEORG MELMER, MICHAEL DEAN, RICHARD ROZMAHEL, JEFFERY L. COLE, DARA KENNEDY, NORIKO HIDAKA, MARTHA ZSIGA, MANUEL BUCHWALD, JOHN R. RIORDAN, LAP-CHEE TSUI, NUMBER 2004 78 LINS

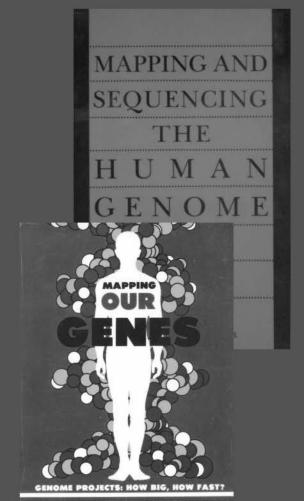


# **Cystic Fibrosis**

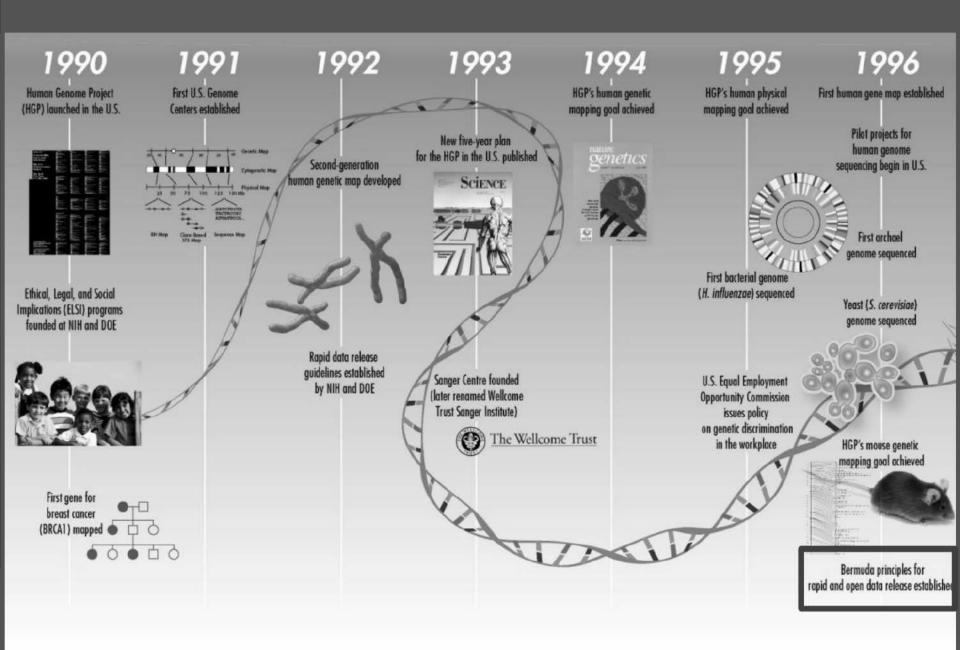
A Major Motivator for the Human Genome

**Project** 

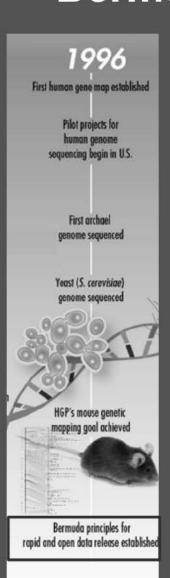
Finding the gene by pure "positional cloning" showed that it could be doneBut it also showed how hard it wasYears of work, millions of dollarsIf similar progress was to be made for the hundreds of other genetic diseases waiting to be understood – many of them much more complex than CF, we needed better research tools

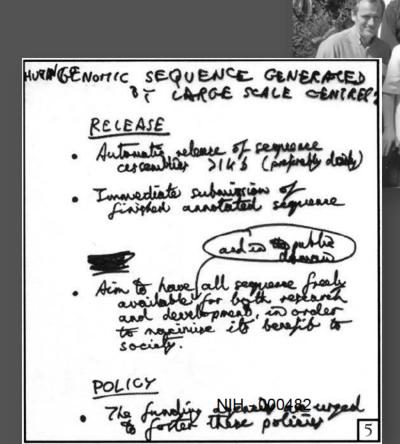






Laying the Foundation for Open Access: Bermuda, 1996







1998

Incorporation of 30,000 genes into human genome map

New five-year plan for the HGP in the U.S. published



1999

Full-scale human sequencing begins



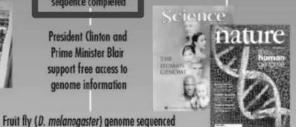
2000

Draft version of human genome sequence completed

President Clinton and Prime Minister Blair support free access to genome information

2001

Draft version of human genome sequence published



2002

Draft version of mouse genome sequence completed and published



Draft version of rat genome sequence completed 2003

Finished version of human genome completed

HGP ends with all goals achieved



E. coli genome sequenced

RIKEN Genomic Sciences Center (Japan) established Sequence of first human chromosome

(chromosome 22) completed

Roundworm (C. elegans) genome sequenced

Mustard cress (A. thaliana)



genome sequenced

10,000 full-length human cDNAs sequenced



Draft version of rice genome sequence completed and published

continued.

Genoscope (French National Genome Sequencing Center) founded

SNP initiative begins

**GTGCT** GTCCT

Chinese National Human Genome Centers (in Beijing and Shanghai) established

Executive order bans genetic discrimination in U.S. federal workplace

#### THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

June 25, 2000

PRESIDENT CLINTON ANNOUNCES THE COMPLETION OF THE FIRST

SURVEY OF THE ENTIRE HUMAN GENOME

Hails Public and Private Efforts Leading to This Historic Achievement

June 26, 2000

Today, at a historic White House event with British Prime Minister Tony Blair, President Clinton announced that the international Human Genome Project and Celera Genomics Corporation have both completed an initial

theguardian

News > Science > Genetics

Scientists finish first draft of DNA blueprint

Interactive guide

Tim Radford, science editor

The Guardian Monday 26 June 2000 03 10 FDT

Scientists in London and Washington will announce today that they have completed the "first draft" of the entire blueprint of human life, described as the most important scientific effort humankind has ever mounted. including splitting the atom and going to the moon.

int for human beings. public and private

nature News

Nature 405, 983-984 (29 June 2000) | doi:10.1038/35016696

World leaders heap praise on human genome landmark

#### Colin Macilwair Science

June 27, 2000

The New york Times





#### Genetic Code of Human Life Is Cracked by Scientists

By NICHOLAS WADE

ASHINGTON, June 26 -- In an achievement that represents a pinnacle of human selfknowledge, two rival groups of scientists said today that they had deciphered the hereditary script, the set of instructions that defines the human organism.



President Clinton and Prime Minister Blair support free access to genome information

2000

Draft version of

human genome

sequence completed



#### NIH NEWS RELEASE

NATIONAL INSTITUTES OF HEALTH

National Human Genome Research Institute

U.S. Department of Engery

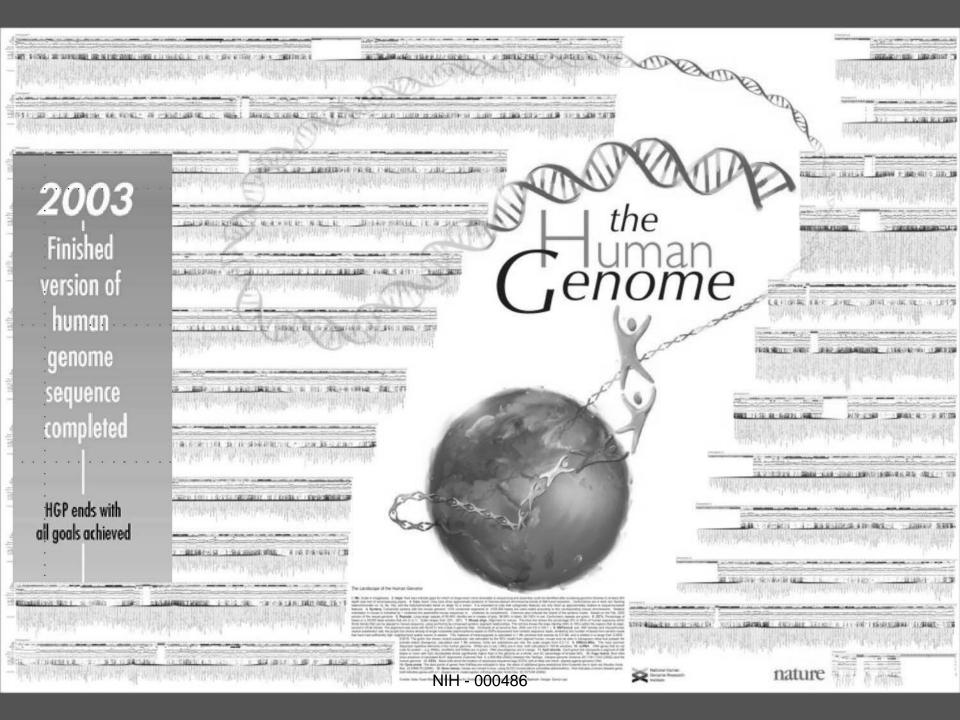
FOR IMMEDIATE RELEASE Monday, June 26, 2000 10:30 a.m. EST

Contact: Cathy Yarbrough, NHGRI (301) 594-0954

International Human Genome Sequencing Consorting Annoog484 "Working Draft" of Human Genome



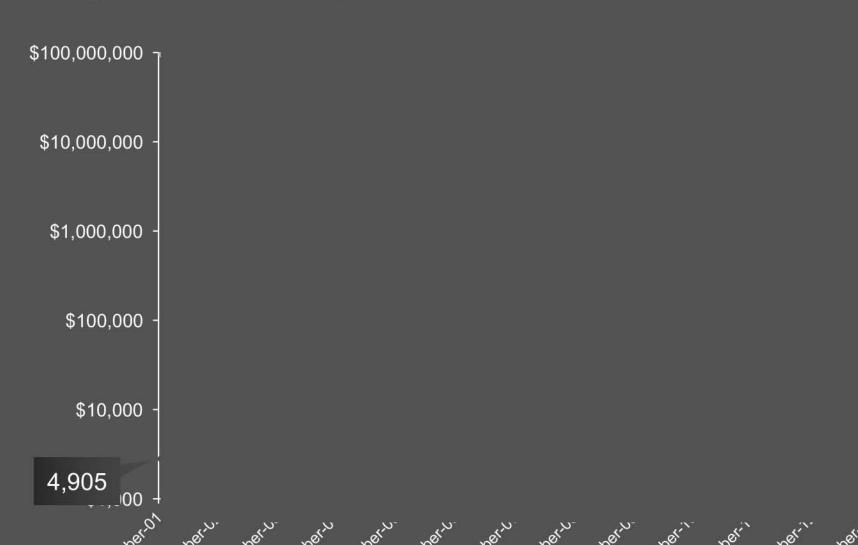






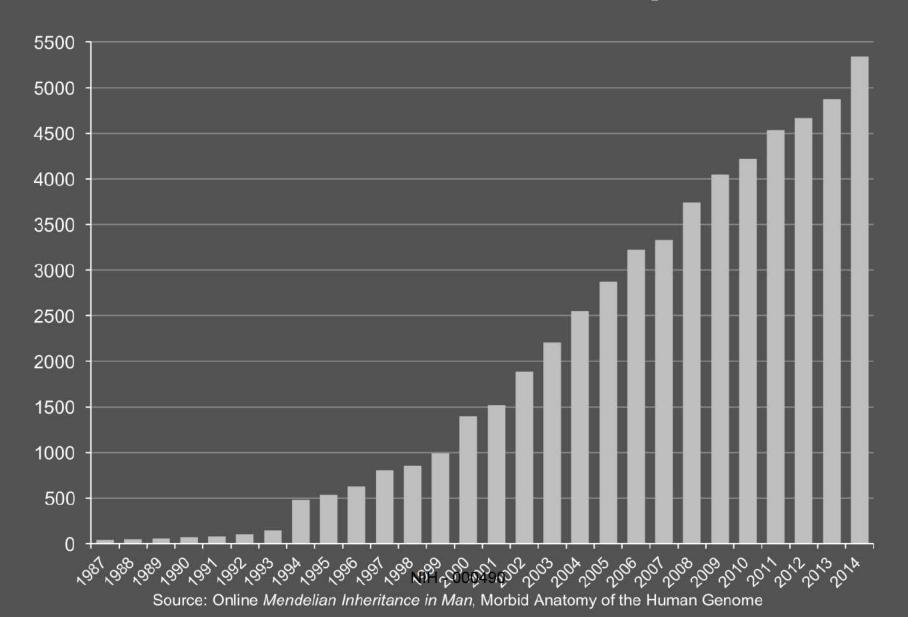


# Cost of Sequencing a Human Genome September 2001-July 2014

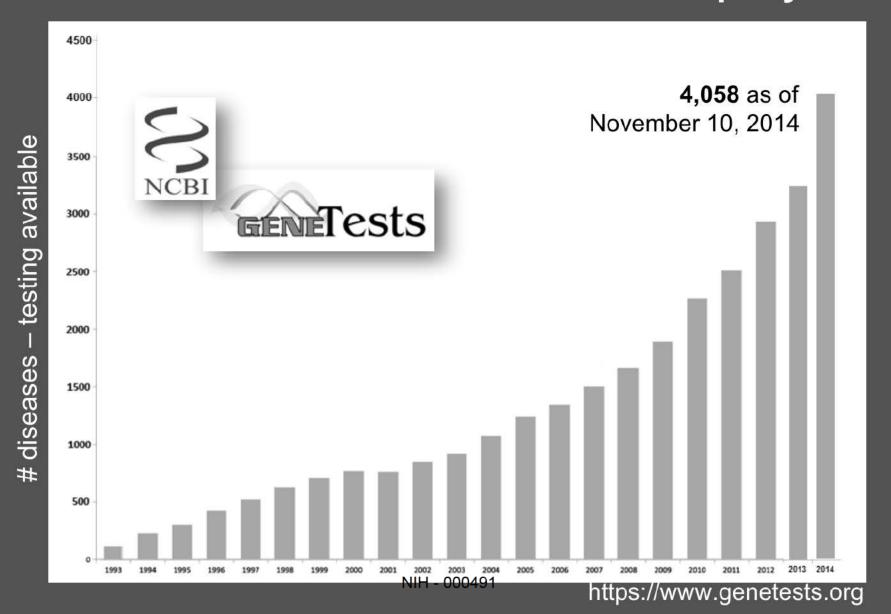


?

## Molecular Basis of Disease Expands...



## ... And Number of Gene Tests Grows Rapidly Too



# Present

THE LANGUAGE OF LIFE



Fran

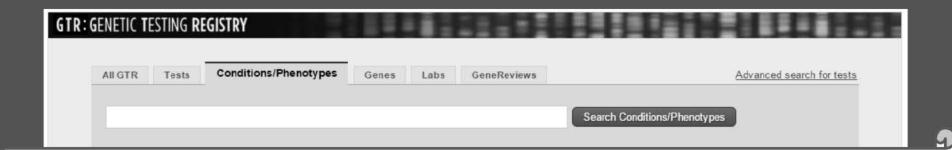
## NIH and Molecular Diagnostics

 NIH supports research in molecular diagnostics toUncover the molecular basis of disease Support innovation in technology and test developmentEvaluate efficacy of molecular diagnosticsNIH launched the Genetic Testing Registry in 2012

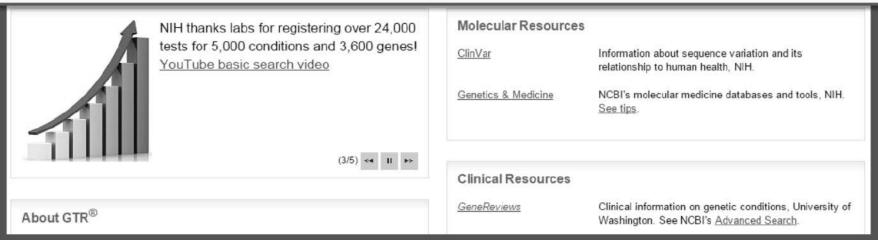


# Genetic Testing Registry (GTR)

www.ncbi.nlm.nih.gov/gtr/



#### With Thanks to AMP and Its Members



# GTR: Provides an Evidentiary Basis for Clinical Genetic Tests

• 24,088 tests, offered by 417 labs in 39 countriesScope:Molecular, cytogenetic and biochemical testsMultiplex panels and arraysSingle gene tests for heritable mutationsIncluding 111 pharmacogenetic tests for 37 drug responsesHLA compatibility tests for transplantationSomatic / cancer tests (N = 209)Research tests (N = 240)Lab services include whole exome sequencing / whole genome sequencing (offered by 31 labs)AMA CPT MoPath codes supportedFewer than 1% of tests report FDA approved/cleared

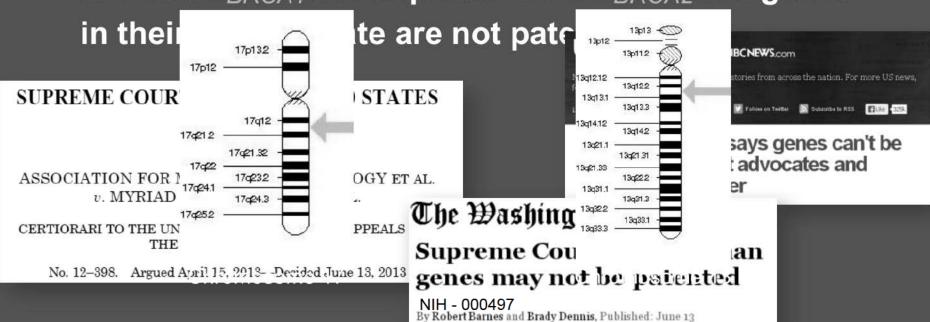
# Cystic Fibrosis carrier screening: Applying NextGen sequencing

November 19, 2013: FDA announced first regulatory clearance of high-throughput DNA sequencing deviceAuthorized broad clinical use of Illumina MiSeqDxAllows fast, full, accurate sequencing of patient's genomePotential applications



## Major Legal Decision for Genomic Medicine: Supreme Court Ruling on Patenting Human Genes

■ 1997/1998: U.S. patents result in exclusive rights for diagnostic testing to Myriad for BRCA1 and BRCA22009: AMPACLU lawsuit filed asserting that patents on these genes should never have been allowed 2043 U.S. Supreme Court reples that genes



## NIH and Molecular Diagnostics

 NIH supports research in molecular diagnostics toUncover the molecular basis of disease Support innovation in technology and test developmentEvaluate efficacy of molecular diagnosticsNIH launched the Genetic Testing Registry in 2012NIH provides tools and resources to help understand the clinical significance of genetic variantsClinVarClinical Genome Resource (ClinGen)

#### ClinVar

## www.ncbi.nlm.nih.gov/clinvar/

 Archive of assertions of clinical significance of genetic variants – not validated by NIHVariations with assertions about clinical significance: 98,184Fully public and freely availableSubmission-driven databasePrimary submissionsExpert-curated submissions; curation support from NCBI staff

ACTGATGGTATGGGGCCAAGAGATATATCT CAGGTACGGCTGTCATCACTTAGACCTCAC CAGGGCTGGGCATAAAAGTCAGGGCAGAGC CCATGGTGCATCTGACTCCTGAGGAGAAGT GCAGGTTGGTATCAAGGTTACAAGACAGGT GGCACTGACTCTCTCTGCCTATTGGTCTAT

About ClinVar

#### ClinVar

ClinVar aggregates information about sequence variation and its relationship to human health.

Using ClinVar Tools NIH - 000499 Related Sites

ACMG Recommendations for Reporting of Incidental Findings

ClinGen

## ClinVar

#### FBN1:c.4786C>T (p.Arg1596Ter) AND Marfan's syndrome

Clinical significance:

pathogenic (Last evaluated: May 2, 2012)

Review status

\*\*\*

Based on: 2 submissions [Details]

Record status: current

Accession: RCV000029744.2

**Review Status** 

Assertion and evidence details

#### Clinical

SignificanceDisease
Association:BenignLikel
y benignUncertain
significanceLikely
pathogenicPathogenicH

as conflictsDrug

response:Confers

sensitivityRisk

factorAssociationProtec tiveHas conflicts

ociety

Help

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ter

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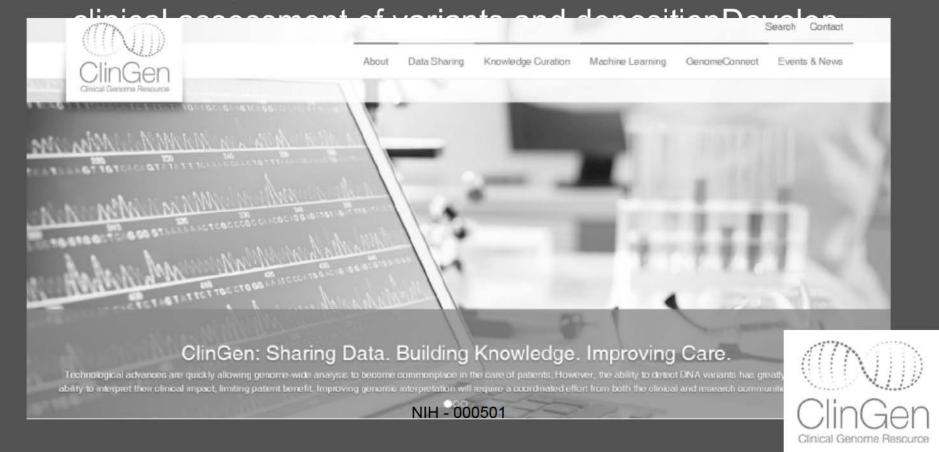
PubMed (3)
[See all records
that cite these
PMIDs]

NIH - 000500

## ClinGen

## www.clinicalgenome.org/

 Purpose: create a central resource of clinically annotated genes and variants to improve understanding of genomic variation; optimize use in medicineGoalsStandardize

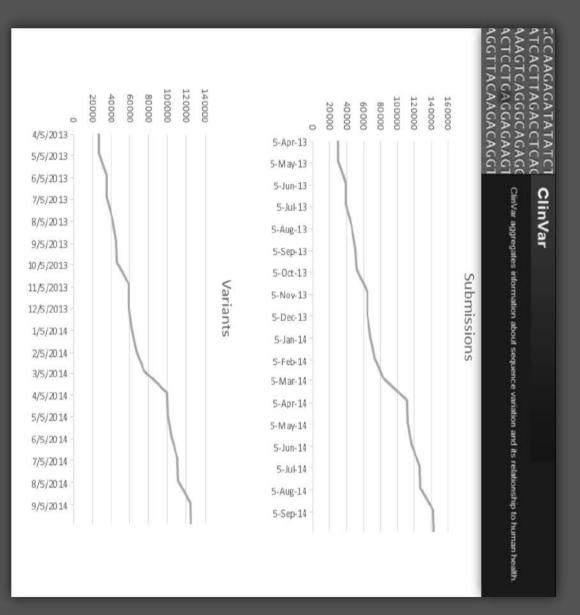


# ClinGen: Clinical Validity Classification

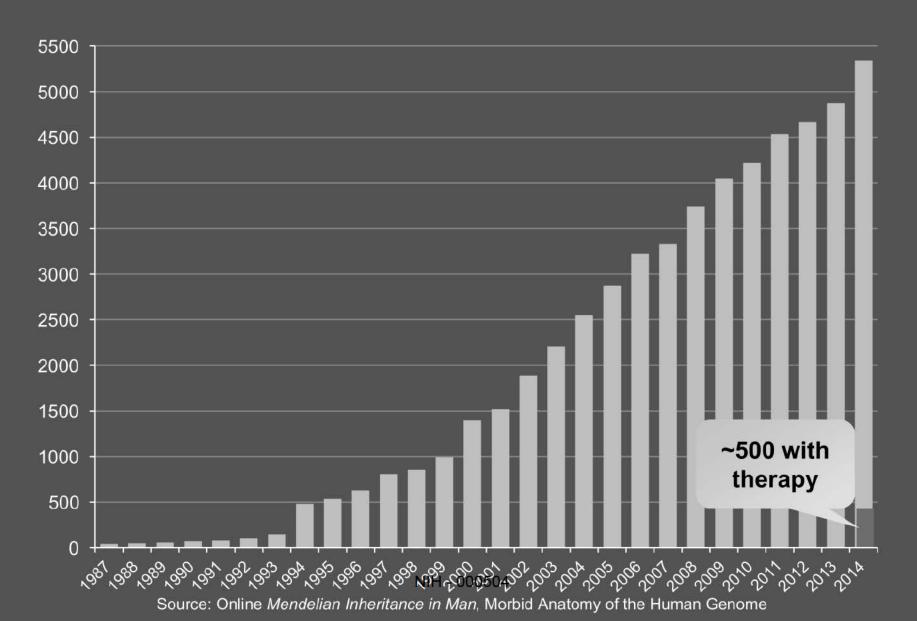
Tiered framework for assessing evidence of association between genes and genetic disorders

Definitive: repeatedly demonstrated in lab and clinic; upheld over time – no valid contradictory evidenceStrong: supported by at least two independent studiesModerate: may not be independently reported, but no valid contradictory evidence has emergedLimited: e.g., <3 observations of pathogenic variant within geneNo evidenceDisputed: evidence refuting is stronger than that supportingEvidence against: evidence refuting is significantly stronger

# ClinGen www.clinicalgenome.org/

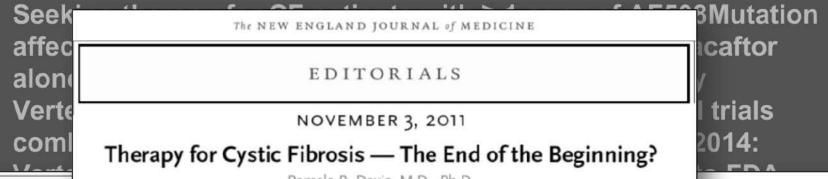


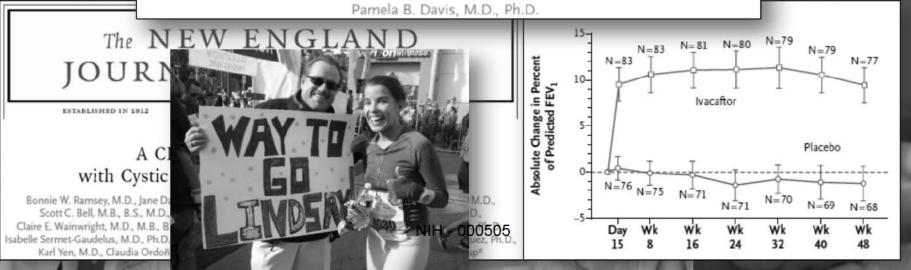
## **Disorders with Known Molecular Basis**



# Cystic Fibrosis From Discovery to Treatment

 2009: CF Foundation/Vertex: ivacaftor (Kalydeco®) found to enhance chloride transport activity of G551D-CFTR in vitro 2011: Phase III clinical trial of ivacaftor provides first proof treatment aimed at genetic defect can improve CF symptomsJanuary 2012: FDA approves ivacaftorToday:





# National Center for Advancing Translational Sciences (NCATS)

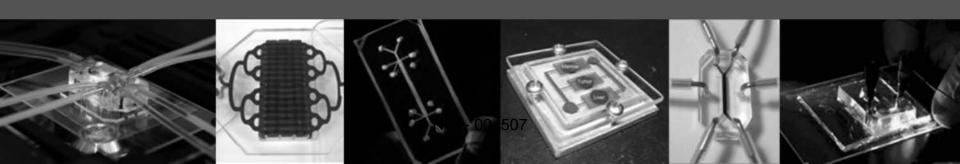
Mission:To catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

# http://ncats.nih.gov/



# An Exemplary NCATS Program: Human Tissue Chip for Drug Screening

■ Goal: develop biochip to screen for safe, effective drugsLiver, heart, lung, other cell typesUse to predict toxicity; efficacyNIH phase 1 awards (2012): to create individual chipsTwelve projects to develop 3-D cellular microsystems representing human organ systems Seven projects to explore potential of stem cells to differentiate into multiple cell typesPhase 2 awards (2014): cell incorporation; organ integrationSupport 11 institutions collaborate over three years



# **Future**

#### THE WALL STREET JOURNAL.

# Francis Collins Says Medicine in the Future Will Be Tailored to Your Genes

FRANCIS S. COLLINS July 7, 2014 3:58 p.m. ET

"Once the stuff of science fiction, the individualized approach to medicine is rapidly approaching reality..."

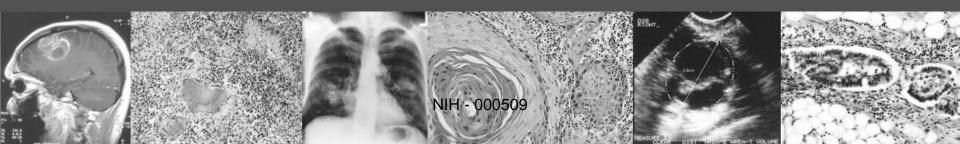
#### The Cancer Genome Atlas

Coordinated effort to accelerate understanding of cancer through genome analysis to improve diagnosis, treatment, and preventionProvides analysis of > 20 types of cancer, includingLeukemia — BrainBreast

LungColon

OvaryBladder

Thyroid



#### The Cancer Genome Atlas Understanding genomics

# The Cancer Genome Atlas: Comparing "Fingerprints" of Cancer Types

Searching for shared genomic fingerprints12 cancer typesTumor samples from 3,300 patients NIH DIRECTOR'S BLOG significantly mutated genes Posted on October 22, 2013 by Dr. Francis Collins shared by subsets of samples across cancer typesPotential significance for customizing treatment for individual patients Therapeu identifying key cellular pathways to find likely

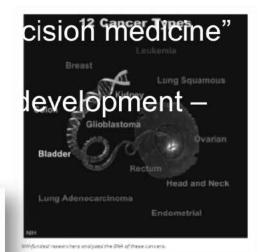
ARTICLE



Mutational landscape and significance across 12 major cancer types

Cyriac Kandoth<sup>1\*</sup>, Michael D. McLellan<sup>1\*</sup>, Fabio Vandin<sup>2</sup>, Kai Ye<sup>1,3</sup>, Beifang Niu<sup>1</sup>, Charles Lu<sup>1</sup>, Mingchao Xie<sup>1</sup>, Qunyuan Zhang<sup>1,3</sup> Joshua F. McMichael<sup>1</sup>, Matthew A. Wyczalkowski<sup>1</sup>, Mark D. M. Leiserson<sup>2</sup>, Christopher A. Miller<sup>1</sup>, John S. Welch<sup>4,5</sup>, Matthew J. Walter<sup>4,5</sup>, Michael C. Wendl<sup>1,3,6</sup>, Timothy J. Ley<sup>1,3,4,5</sup>, Richard K. Wilson<sup>1,3,5</sup>, Benjamin J. Raphael<sup>2</sup> & Li Ding<sup>1,3,4,5</sup>

Different Cancers Can Share Genetic Signatures



disease of the genome. It arises when genes involved in promoting or suppressing cell ain mutations that disturb the normal stop and go signals. There are more than 100 bes of cancer, most of which derive their names and current treatment based on their igin-breast, colon, or brain, for example. But because of advances in DNA sequencing that soon may be about to change.

ttp://directorsblog.nih.gov/

# The Human Microbiome Project

INSIGHT FEATURE

NATURE Vol 449 18 October 2007

#### nature

#### The Human Microbiome Project

Peter J. Turnbaugh, Ruth E. Ley, Micah Hamady, Claire M. Fraser-Liggett, Rob Knight & Jeffrey I. Gordon

#### ARTICLE

14 JUNE 2012 | VOL 486

# A framework for human microbiome research

The Human Microbiome Project Consortium\*

#### **ARTICLE**

14 JUNE 2012 | VOL 486

# Structure, function and diversity of the healthy human microbiome

The Human Microbiome Project Consortium\*





# Our Microbiomes and Our Health: Type 2 Diabetes

**BRIEF COMMUNICATIONS** 

NATURE Vol 444 21/28 December 2006

MICROBIAL ECOLOGY

## Human gut mi

Ruth E. Ley, Peter J. Turnt

# NIH DIRECTOR'S BLOG

Taking a New Look at Artificial Sweeteners luce glucose

Posted on October 7, 2014 by Dr. Francis Collins

### ARTICLE

### A metagenome-v gut microbiota in

Junjie Qin<sup>1</sup>\*, Yingrui Li<sup>1</sup>\*, Zhiming Cai<sup>2</sup>\*, Shenghui Li Yuanlin Guan<sup>1</sup>, Dongqian Shen<sup>1</sup>, Yangqing Peng<sup>1</sup>, Dor Junhua Li<sup>1</sup>, Lingchuan Han<sup>3</sup>, Donghui Lu<sup>3</sup>, Petxian W Xiaoping Li<sup>3</sup>, Weineng Chen<sup>1</sup>, Ran Xu<sup>1</sup>, Mingbang Wa Torben Hansen<sup>5</sup>, Gaston Sanchez<sup>6</sup>, Jeroen Raes<sup>7,8</sup>, Gw Emmanuelle LeChatelier<sup>9</sup>, Pierre Renault<sup>9</sup>, Nicolas Po Weimou Zheng<sup>4</sup>, Songgang Li<sup>1</sup>, Huanming Yang<sup>1</sup>, Jian Karsten Kristiansen<sup>1,15</sup> & Jun Wang<sup>1,5,13</sup>



### impaired and diabetic glucose control

Fredrik H. Karlsson<sup>1</sup>\*, Valentina Tremaroli<sup>2</sup>\*, Intawat Nookaew<sup>1</sup>, Göran Bergström<sup>2</sup>, Carl Johan Behre<sup>2</sup>, Björn Fagerberg<sup>2</sup>, Jens Nielsen<sup>1</sup> & Fredrik Bäckhed<sup>2,1</sup>

NIH - 000512

R 2014 | VOL 514 | NATURE | 181

### luce glucose he gut microbiota

stoph A. Thaiss<sup>1</sup>, Ori Maza<sup>1</sup>, David Israeli<sup>3</sup>, Harmelin<sup>8</sup>, Ilana Kolodkin-Gal<sup>9</sup>, Hagit Shapiro<sup>1</sup>,

59, 789-799, November 6, 2014

### aut Microbiome

Timothy D. Spector, Andrew G. Clark,

# Undiagnosed Diseases and NIH

• Undiagnosed Diseases Program (UDP)Patients with longstanding, undiagnosed medical conditions are seen at NIH Clinical CenterUDP's NIH-wide staff, led by Dr. William Gahl, has:Evaluated ~3,000 medical recordsAccepted ~700 casesDetermined some diagnosis in ~25%Now: National Undiagnosed Diseases NetworkWill expand program's data, approaches



# Identifying Causes of Rare Diseases: DADA2

Mystery: what wastrokes – in 3 you
 Center?"Detecting
 investigatedMolerevealed

2 mutated copie

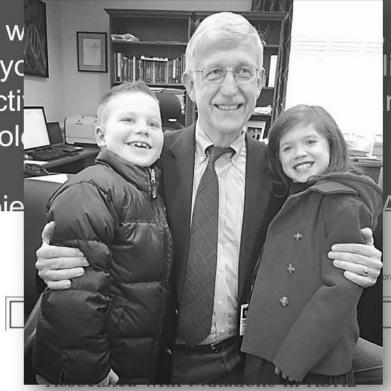
blood vessel of

deficiency →

→ fevers, rash "DADA2"Impli

better treatme

promise of ne



Q. Zhou, D. Yang, A.K. Ombrello, Andrey V. Zavialov, C. Toro, Anton V. Zavialov, D.L. Stone, J.J. Chae, S.D. Rosenzweig, K. Bishop, K.S. Barron, H.S. Kuehn, P. Hoffmann, A. Negro, W.L. Tsai, E.W. Cowen, W. Pei, J.D. Milner, C. Silvin, T. Heller, D.T. Chin, N.J. Patronas, J.S. Barber, C.-C.R. Lee, G.M. Wood, A. Ling, S.J. Kelly, D.E. Kleiner, J.C. Mullikin, N.J. Ganson, H.H. Kong, S. Hambleton, F. Candotti, M.M. Quezado, K.R. Calvo, H. Alao, B.K. Barham, A. Jones, J.F. Meschia, B.B. Worrall, S.E. Kasner, S.S. Rich, R. Goldbach-Mansky, M. Abinun, E. Chalom, A.C. Gotte, M. Punaro, V. Pascual, J.W. Verbsky, T.R. Torgerson, N.G. Singer, T.R. Gershon, S. Ozen, O. Karadag, T.A. Fleisher, E.F. Remmers, S.M. Burgess, S.L. Moir, M. Gadina, R. Sood, M.S. Hershfield, M. Boehm, D.L. Kandler, and O.O. M.S. Hershfield, M. Boehm, D.L. Kandler, and M.S. Hershfield, M. Boehm,

rashes – and linical mural Program sequencing

△2Enzyme key for ceADA2

→ inflammation

re condition,

2, promise of

∍r a stroke,

ion – treatment

# Personalized Medicine: A future dream



# Story of Hope

April 14, 2003: baby Hope is bornFamil( completionApril 2013Scientists celebra of HGP's completionHope's family cele 10th2023Hope's aunt dies at age 53 of uses Surgeon Ger family medical genome a than normalHop

toolDoctor en

international Consc

Ail Goals Achieved; Ne

BETHESDA, Md., April 14, 2003.

The International Human Genome Consortium, led in the United States by al Human Genome Research Institu and the Department of Energy (DOE nounced the successful completion a Genome Project more than two year schedule.



| Trait               | Risk    |
|---------------------|---------|
| Alzheimer's Disease | Average |
| Breast Cancer       | Average |
| Colon Cancer        | Low     |
| Heart Disease       | High    |



NIH - 000516

# **Story of Hope**



# Story of Hope

2103Hope celebrates her 100th with a night of dancing



NIH - 000518

# The essential goal of precision medicine

Keep Hope Alive!





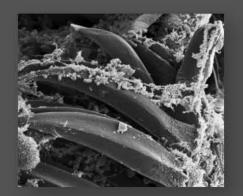


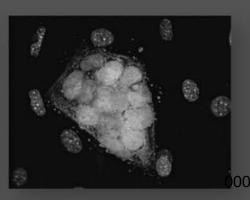


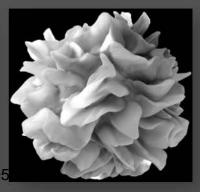
# H... Turning Discovery Into Health

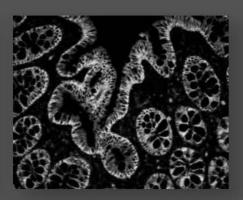
directorsblog.nih.gov @NIHDirector











From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 31 Oct 2014 14:08:16 +0000

To: Andrew.Plump@sanofi.com

Cc: Wholley, David (FNIH) [T]

Subject: RE: AMP

Hi Andy,

I'm very glad to hear that you are willing to explore a solution that will keep you engaged in AMP. Yes, please reach out to Phil and see what can be worked out. It would be particularly important to have your input for the Extended Executive Committee meeting, which has now been scheduled for November 21 from 4-5:30 PM EST.

All the best, Francis

**From:** Andrew.Plump@sanofi.com [mailto:Andrew.Plump@sanofi.com]

Sent: Thursday, October 30, 2014 8:36 PM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Wholley, David (FNIH) [T]

Subject: RE: AMP

Hi Francis,

Thanks you for reaching out and in your characteristic energetic and charismatic manner, encouraging me to say on in this role!

As you know, I believe deeply in what you've put together with AMP and am committed to supporting it. My concern is whether I am able to engage sufficiently to add the necessary level of value. As I discussed briefly with David, I don't want to take up a spot on this important effort and block someone else from stepping in, who might be more engaged and add more direct value. I sense that my sponsorship and intermittent guidance has been helpful to the team, but not sure whether this is sufficient.

I had been planning to reach out to you directly to discuss, but sensitive to your time, I have decided to first discuss this with Phil Smith and see what he thinks.

I don't see relief in my schedule for the coming weeks, particularly now with Chris having left Sanofi, coupled with our budget review cycle coming to a close, but I am eternally optimistic given the priority I place on this that I will be able to work my way back into the mix.

My suggestion is that we stay as is for now. I will find time in the coming weeks to discuss with Phil. Then, perhaps you and I can talk about the best way to handle.

Thanks, Andy From: Collins, Francis (NIH/OD) [E] [mailto (b) (6)

Sent: Thursday, October 30, 2014 7:48 PM

**To:** Plump, Andrew R&D/FR **Cc:** Wholley, David (FNIH) [T]

Subject: AMP

Hey there Andy,

I spoke this afternoon with David Wholley about progress on the AMP collaboration. He assured me that things are going quite well with all three areas of focus – but mentioned that you were struggling a bit about whether you still had the time to serve as a Steering Committee co-chair for the T2D project.

I just thought I'd check in with you about this. I am personally very hopeful that you can continue in this role — as your expertise is exactly what's needed to keep the momentum going in this exciting area. Can you figure out a way to make this work?

I'm sorry to pose this question to you at a time where no doubt there is some tumult at Sanofi – but I'd appreciate a sense from you about whether this can still work. Personally | really hope so!!

Best, Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 31 Oct 2014 14:06:01 +0000

To: Wholley, David (FNIH) [T]

Subject: RE: AMP

Sounds good to me.

From: Wholley, David (FNIH) [T]
Sent: Friday, October 31, 2014 7:55 AM
To: Collins, Francis (NIH/OD) [E]

Subject: Re: AMP

(b) (5)

From: <Collins>, Francis Collins (b) (6)

**Date:** Friday, October 31, 2014 at 6:15 AM **To:** David Wholley <<u>dwholley@fnih.org</u>>

Subject: FW: AMP

(b) (5)

FC

From: Andrew.Plump@sanofi.com [mailto:Andrew.Plump@sanofi.com]

Sent: Thursday, October 30, 2014 8:36 PM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Wholley, David (FNIH) [T]

Subject: RE: AMP

Hi Francis,

Thanks you for reaching out and in your characteristic energetic and charismatic manner, encouraging me to say on in this role!

As you know, I believe deeply in what you've put together with AMP and am committed to supporting it. My concern is whether I am able to engage sufficiently to add the necessary level of value. As I discussed briefly with David, I don't want to take up a spot on this important effort and block someone else from stepping in, who might be more engaged and add more direct value. I sense that my sponsorship and intermittent guidance has been helpful to the team, but not sure whether this is sufficient.

I had been planning to reach out to you directly to discuss, but sensitive to your time, I have decided to first discuss this with Phil Smith and see what he thinks.

I don't see relief in my schedule for the coming weeks, particularly now with Chris having left Sanofi, coupled with our budget review cycle coming to a close, but I am eternally optimistic given the priority I place on this that I will be able to work my way back into the mix.

My suggestion is that we stay as is for now. I will find time in the coming weeks to discuss with Phil. Then, perhaps you and I can talk about the best way to handle.

Thanks, Andy

From: Collins, Francis (NIH/OD) [E] [mailto: (b) (6)

Sent: Thursday, October 30, 2014 7:48 PM

**To:** Plump, Andrew R&D/FR **Cc:** Wholley, David (FNIH) [T]

Subject: AMP

Hey there Andy,

I spoke this afternoon with David Wholley about progress on the AMP collaboration. He assured me that things are going quite well with all three areas of focus – but mentioned that you were struggling a bit about whether you still had the time to serve as a Steering Committee co-chair for the T2D project.

I just thought I'd check in with you about this. I am personally very hopeful that you can continue in this role – as your expertise is exactly what's needed to keep the momentum going in this exciting area. Can you figure out a way to make this work?

I'm sorry to pose this question to you at a time where no doubt there is some tumult at Sanofi – but I'd appreciate a sense from you about whether this can still work. Personally | really hope so!!

Best, Francis

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Mon, 22 Dec 2014 12:25:12 +0000

To: Cuss, Francis
Subject: RE: AMP

Hi Francis,

Thanks for your thoughtful note.

(b) (4)

Your advice about optimizing the telecoms is right on target - I am resonating!!

Have a wonderful holiday,

Francis

From: Cuss, Francis [mailto:francis.cuss@bms.com]

Sent: Saturday, December 20, 2014 7:17 AM

To: Collins, Francis (NIH/OD) [E]

Subject: AMP

Dear Francis,

(b) (4)

On another matter mentioned yesterday, I wanted to re-emphasize how important it is for us to find a way to manage the content and maintain interest during these broadly attended and important communication telecoms to the broader AMP leadership. Managing this sort of meeting effectively has been a particular issue for us in BMS also, so I'm sympathetic to the challenge, and making it better is a particular interest of mine. As a result of my experience in Pharma I'm also very much aware at how easy it is to lose the engagement of the audience if the presentations drag on, the agenda gets telescoped and the questions don't get answered. The watch out for us was that when less than optimal meetings occur regularly, busy, time-disciplined people tend to deprioritize subsequent meetings and not attend. I don't think there is a "magic bullet" solution for this, and many of the suggestion offered by Bob and others can be effective if properly executed.

To summarize what has transformed our meetings are firstly strong norms around everyone getting the meeting content from the pre-reads beforehand; secondly commissioning the leaders of the discussions

not to provide content/information on what everyone already agrees on, but to indentify the issues, provide options and solicit opinions/questions and thirdly to have the timing of the meeting agenda rigorously observed (i.e. everyones accountable for the time they use). Applying these simple rules in BMS has resulted in great improvements in the engagement of our meeting participants, in the speed of our decision-making and about a 50% reduction in the time we spend in meetings. It has specifically enhanced our ability to discuss and make important decisions on highly complex scientific and medical issues and make them accessible to a multi-disciplinary set of attendees (i.e. not just the experts in an area).

I know it all sounds miraculous, but I can't say it's been easy to achieve, because there is a significant adjustment cost for many people and a new set of norms has to be observed: namely that these sort of meetings take a lot of preparation both by the topic leaders and participants, they are not the right forum for lecturing, and that if you're not on topic you're actually irrelevant and wasting the time of everyone. One of the measures of a this sort of change in meeting culture is that meetings running this way tend to end early, because the agendas are more focused and only the issues get discussed. My impression is that the AMP monthly meetings are a model of this, and we did indeed finish early yesterday!

Let me finish by congratulating you on the progress AMP has made this year. I think the success to date reflects the importance of clear leadership and focused shared objectives in the precompetitive space.

With best wishes to you and your family for the Holidays and 2015

Francis

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From: Collins, Francis (NIH/OD) [E] Sent: Fri, 21 Nov 2014 13:15:13 +0000

Dolsten, Mikael To:

Cc: Wholley, David (FNIH) [T]

Subject: RE: Dividing up the introduction for AMP tomorrow?

Yes, start on slide 4 (The Challenge) -- but go through slide 7 (AMP Research Topics). Slide 7 doesn't need to be presented in detail, however, since each of the projects will be discussed by the team leads.

Then I'll pick up on Slide 8.

### Best, Francis

----Original Message----

From: Dolsten, Mikael [mailto:Mikael.Dolsten@pfizer.com]

Sent: Friday, November 21, 2014 8:02 AM

To: Collins, Francis (NIH/OD) [E]

Cc: Dolsten, Mikael; Wholley, David (FNIH) [T]

Subject: Re: Dividing up the introduction for AMP tomorrow?

### Francis

I reopened the material in a new device and assume that I start on page 4 labeled "The challenge" and end on slide 7 labeled "How we got here ", right?

Look forward to the call

Mikael

### Sent from my iPhone

> On Nov 20, 2014, at 13:05, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

> HI Mikael,

> I am looking forward to the AMP Extended Steering Committee call tomorrow afternoon. As you can see from the agenda (slide 3 in the attached file), you and I are doing the first ten minutes or so, reminding people of the origins of AMP and setting the stage for the specific project discussions.

> How about you do slides 4-7 (and 7 won't require a lot of time, since we will be going over the details of the projects in the main body of the call), and I do 8 - 11? Or if you'd prefer, we can flip that around – I'd be fine with either option.

> Just let me and David know so we can orchestrate accordingly.

> All the best, Francis

> < AMP Ext EC 11-21-2014 slides 19 Nov-FINAL.pptx>

NIH - 000527

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Tue, 4 Nov 2014 18:14:15 +0000

 To:
 Wholley, David (FNIH) [T]

Subject: RE: Schizophrenia and AMP

(b) (5)

FC

From: Wholley, David (FNIH) [T]

Sent: Tuesday, November 04, 2014 12:58 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Schizophrenia and AMP

Francis,

(b) (5)

David

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Fri, 2 Jan 2015 01:08:59 +0000

To: Wholley, David (FNIH) [T];Smith, Philip (NIH/NIDDK) [E]
Cc: Hudson, Kathy (NIH/OD) [E];Rodgers, Griffin (NIH/NIDDK) [E]

Subject: Altshuler and AMP T2D

Hi David and Phil,

I had occasion to speak by phone with Jeff Leiden a few days ago. As you know, Jeff is the CEO of Vertex, and so he will be David Altshuler's new boss. I let him know how important David's leadership has been in the development of the knowledge portal for T2D at Broad, and expressed hopes that David would continue to be available for advice about its operation, even as he transitions into a very busy job at Vertex. Jeff was accommodating – basically saying that if David felt his input was necessary for continued development of the knowledge portal and if that could be done with a modest time commitment, he (Jeff) would not object.

Of course when I spoke with David himself about this just before his announcement, he expressed confidence that his T2D role at Broad could be nicely accommodated by other team members, especially Jose Flores.

Just thought I'd pass this along.

**Francis** 

From: Collins, Francis (NIH/OD) [E]

Sent: Fri, 6 Feb 2015 12:33:16 +0000

To: christine.jenkins@merck.com

Cc: Wholley, David (FNIH) [T]; Wood, Gretchen (NIH/OD) [E]

Subject: FW: Need a few minutes for a phone call on AMP

Dear Christine,

I'm told that you might be able to get a message to Roger Perlmutter – on the chance that the one I sent yesterday didn't reach him.

Thanks,

Francis Collins Director, NIH

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, February 05, 2015 3:26 PM

To: 'roger.perlmutter@merck.com'

Cc: Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]

Subject: Need a few minutes for a phone call on AMP

Hi Roger,

I need 5 – 10 minutes with you by phone to discuss the type 2 diabetes project of the Accelerated Medicines Partnership. We've been trying to set this up by calling your support staff, but they are VERY effective in building a hedge around you!

Might your assistant liase with Gretchen Wood (cc'd here, available at 6) (6) to find a good time?

Thanks, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Mon, 23 Feb 2015 02:41:38 +0000

To: Wholley, David (FNIH) [T]; Smith, Philip (NIH/NIDDK) [E]

Subject: FW: Next steps for AMP
Attachments: PStein CV 2015.doc

(b) (5)

From: Perlmutter, Roger M [mailto:roger.perlmutter@merck.com]

Sent: Sunday, February 22, 2015 6:01 PM

To: Collins, Francis (NIH/OD) [E]; Miletich, Joseph

Cc: Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Jenkins, Christine S.; Smith, Philip

(NIH/NIDDK) [E]; Rodgers, Griffin (NIH/NIDDK) [E]

Subject: RE: Next steps for AMP

#### Francis:

After considerable internal discussion, I have asked Peter Stein to serve on the T2D panel. Peter, as you may know, is an extremely gifted clinical scientist with a very broad background in diabetes research (he and Andy Plump worked together here on the first DPP4 inhibitor, and he was also intimately involved in registering the leading SGLT2 antagonist with JNJ). Peter knows the needs of the T2D field from a biomarker perspective extraordinarily well, and he works closely with those in our laboratories who seek insight into markers of disease using large genomic data sets. I have attached a copy of Peter's CV, for your interest.

Also, Joe Miletich, whom you know, has agreed to serve on the Extended Executive Committee. I have copied him on this e-mail, so that you and your staff will have his coordinates.

I think that these two appointments will position us to contribute in exactly the way that you suggest.

With all best wishes,

**RMP** 

From: Collins, Francis (NIH/OD) [E] [mailto (b) (6)]

Sent: Sunday, February 22, 2015 1:13 AM

To: Perlmutter, Roger M

Cc: Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Jenkins, Christine S.; Smith, Philip

(NIH/NIDDK) [E]; Rodgers, Griffin (NIH/NIDDK) [E]

Subject: Next steps for AMP

Hi Roger,

I'm glad we were able to speak a week ago about the status of the Accelerated Medicines Partnership (AMP), and my hopes for a major continuing role for Merck. As I mentioned, progress is truly gratifying in this unprecedented partnership, but it is critical to keep the momentum going — and for that purpose

it is essential that both the public and private partners provide appropriate scientific input at a high level.

For context, I attach the membership of the leadership teams for AMP (as of November 2014), prior to two recent changes that caused me to call you.

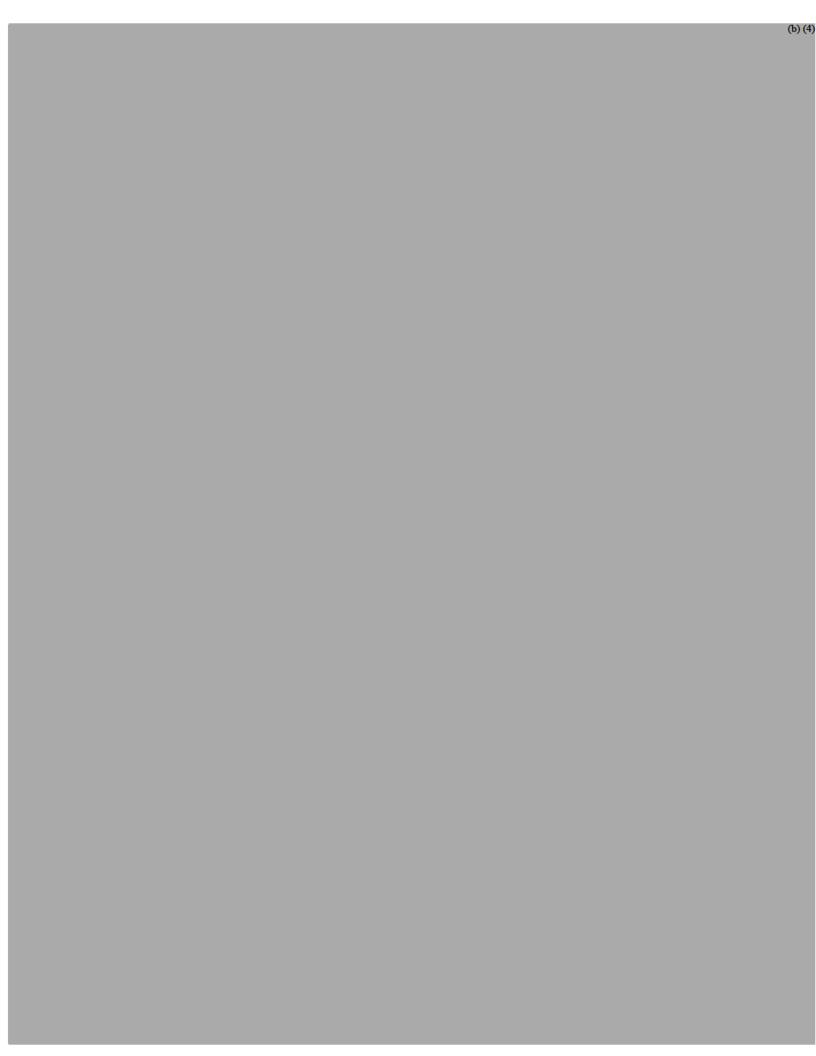


Please let me know your thoughts. I really want to be sure that Merck is a deeply engaged participant in this experiment!

Best, Francis

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From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 5 Feb 2015 20:25:44 +0000
To: roger.perlmutter@merck.com

Cc: Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]

Subject: Need a few minutes for a phone call on AMP

Hi Roger,

I need 5 – 10 minutes with you by phone to discuss the type 2 diabetes project of the Accelerated Medicines Partnership. We've been trying to set this up by calling your support staff, but they are VERY effective in building a hedge around you!

Might your assistant liase with Gretchen Wood (cc'd here, available at (b) (6) to find a good time?

Thanks, Francis

From: Collins, Francis (NIH/OD) [E]

Sent: Sun, 22 Feb 2015 06:13:00 +0000

To: roger.perlmutter@merck.com

Cc: Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH)

[T];christine.jenkins@merck.com;Smith, Philip (NIH/NIDDK) [E];Rodgers, Griffin (NIH/NIDDK) [E]

Subject: Next steps for AMP

Attachments: AMP Governance and Membership 2014.pptx

Hi Roger,

I'm glad we were able to speak a week ago about the status of the Accelerated Medicines Partnership (AMP), and my hopes for a major continuing role for Merck. As I mentioned, progress is truly gratifying in this unprecedented partnership, but it is critical to keep the momentum going – and for that purpose it is essential that both the public and private partners provide appropriate scientific input at a high level.

For context, I attach the membership of the leadership teams for AMP (as of November 2014), prior to two recent changes that caused me to call you.



Please let me know your thoughts. I really want to be sure that Merck is a deeply engaged participant in this experiment!

Best, Francis

## AMP Governance and Membership

### **Extended Executive Committee**

 Bill Chin, PhRMABill HaiDoug Williams, Biogen-J&JJim Sullivan, IdecJanet Woodcock, AbbViePatrick Vallance, FDATachi Yamada, GSKRupert Vessey, TakedaElias Zerhouni, Merck Sanofi Core Executive Committee
Co-chairsFrancis Mikael Dolsten, Pfizer
Collins, NIH
MembersFrancis Cuss<sub>Rick Lifton</sub>, YaleJan Lundberg,
BMSRichard Hodes, LillyGriffin Rodgers,
NIAKathy Hudson, NIDDKSharon Terry, Genetic
NIHSteve Katz, NIAMSAlliance

### Executive and Steering Committee Support

 David Wholley, FNIHRosa Canet-Aviles, FNIHMaria Vassileva, FNIHSteve Hoffmann, FNIHSanya Fanous Whitaker, FNIH

### Alzheimer's disease Steering Committee

Co-chairsMike Decker, AbbVieNeil Buckholtz, NIAEC LiaisonRichard Hodes, NIAMembersMaria Carrillo, ALZHoward Fillit, ADDFXiaoming Guan, GSKTim Harris, Biogen IdecWalter Koroshetz, NINDSMark Mintun, Lilly Pat Walicke, NINDSBilly Dunn, FDA

### Type 2 DiabetesSteering Committee

Co-chairsAndy Plump, SanofiPhil Smith, I

### RA, SLE Steering Committee

Co-chairsMarty Hodge, PfizerBob
Carter, NIAMSEC LiaisonSteve Katz,
NIAMSMembersChristopher Arendt,
SanofiJeff Browning,
ALR/LRICarolyn Cuff, AbbVieMarc
Levesque, AbbVieAndrey Loboda,
MerckSatwant Narula, BMSLisa
Olson, AbbVieDan Rotrosen,
NIAIDDavid Shuey, Arthritis
FoundationJonathan Zalevsky,
TakedaDennis Zaller, Merck

NIH - 000540

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Wed, 11 Feb 2015 16:26:29 +0000

To: Wholley, David (FNIH) [T]

Cc: Wood, Gretchen (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];Gadbois, Ellen

(NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]

Subject: RE: AMP Extended EC Meeting

May 1 looks good, let's lock it in.

From: Wholley, David (FNIH) [T]

Sent: Wednesday, February 11, 2015 10:33 AM

To: Collins, Francis (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E];

Melencio, Cheryl (FNIH) [T]

Subject: AMP Extended EC Meeting

### Francis:

Here is our progress so far on getting dates for the AMP Extended EC call. The best date for getting all the industry folks on board looks like Friday, May 1 (I don't know what it is about Friday afternoons...) though we may have issues with a few NIH folks. Can you have a look and let me know your thoughts, so we can get something locked down on the calendars?

Thank you David From: Collins, Francis (NIH/OD) [E]

Sent: Wed, 7 Jan 2015 17:22:41 +0000

To: Smith, Philip (NIH/NIDDK) [E]

Subject: RE: AMP T2D SC co-chair

I agree that Plenge would be terrific. He was my host a couple of months ago when I gave a talk at Merck. Let me know if you'd like me to approach him, or to speak with Perlmutter.

FC

From: Smith, Philip (NIH/NIDDK) [E]

Sent: Wednesday, January 07, 2015 12:14 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** RE: AMP T2D SC co-chair

Quick follow up.

I think that Roger Plenge is our best bet. There is a very nice website describing his position and goals.

### http://www.plengegen.com/robert-plenge/

I will be in Keystone this weekend and will have an opportunity to talk informally with a few pharma folks who are on the Keystone Scientific Advisory Board.

I need to touch base with David Wholley about his conversation with Alan Shuldiner. While he was going to try to get Regeneron to contribute to the RA Lupus Partnership, Alan may be more interested in AMP T2D.

I would like to get a new chair in place next week as things are accelerating.

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, December 19, 2014 8:34 AM

To: Smith, Philip (NIH/NIDDK) [E]

Cc: Wholley, David (FNIH) [T]; Wood, Gretchen (NIH/OD) [E]

Subject: AMP T2D SC co-chair

If you can, call me right after this EC call. (b) (6)

 From:
 Collins, Francis (NIH/OD) [E]

 Sent:
 Thu, 19 Feb 2015 16:06:33 +0000

 To:
 Smith, Philip (NIH/NIDDK) [E]

Cc: Wholley, David (FNIH) [T];Rodgers, Griffin (NIH/NIDDK) [E];Gadbois, Ellen

(NIH/OD) [E]

Subject: RE: AMP T2D SC co-chair

Hi Phil,

Sorry, I should have cc'd you on the note below! If I don't hear something back from Roger by Monday, I will ping him again.

(b) (5)

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, February 10, 2015 5:57 PM

**To:** Wholley, David (FNIH) [T] **Cc:** Gadbois, Ellen (NIH/OD) [E]

Subject: Perlmutter

Hi David,



FC

From: Smith, Philip (NIH/NIDDK) [E]

Sent: Thursday, February 19, 2015 10:41 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: AMP T2D SC co-chair

Just following up here. David Wholley and I talked about this and

(b)(5)

(b)(5)

From: <Collins>, "Francis [E] (NIH/OD)" (b) (6)

**Date:** Wednesday, January 7, 2015 at 12:22 PM **To:** Philip Smith (b) (6)

Subject: RE: AMP T2D SC co-chair

I agree that Plenge would be terrific. He was my host a couple of months ago when I gave a talk at Merck. Let me know if you'd like me to approach him, or to speak with Perlmutter.

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To: Smith, Philip (NIH/NIDDK) [E]

Cc: Wholley, David (FNIH) [T]; Wood, Gretchen (NIH/OD) [E]

Subject: AMP T2D SC co-chair

| If you can, call me right after this EC ca | AH. |
|--------------------------------------------|-----|

(b) (6)

From: Collins, Francis (NIH/OD) [E]

Sent: Tue, 24 Feb 2015 10:39:29 +0000

To: Perlmutter, Roger M; Miletich, Joseph

Cc: Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Jenkins, Christine

S.; Smith, Philip (NIH/NIDDK) [E]; Rodgers, Griffin (NIH/NIDDK) [E]

Subject: RE: Next steps for AMP

Dear Roger,

Many thanks for your personal attention to this issue, and for this excellent proposed plan. Peter Stein will be terrific as co-chair of the T2D panel, and I will ask David Wholley (FNIH) and/or Phil Smith (NIDDK) to reach out to him to discuss how to get this underway.

I will also warmly welcome Joe Miletich to the Extended Executive Committee – his experience and wise advice will be greatly appreciated as AMP moves forward. David Wholley will reach out to him about next steps.

Best personal regards, Francis

From: Perlmutter, Roger M [mailto:roger.perlmutter@merck.com]

Sent: Sunday, February 22, 2015 6:01 PM

To: Collins, Francis (NIH/OD) [E]; Miletich, Joseph

Cc: Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Jenkins, Christine S.; Smith, Philip

(NIH/NIDDK) [E]; Rodgers, Griffin (NIH/NIDDK) [E]

Subject: RE: Next steps for AMP

Francis:

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With all best wishes,

RMP

From: Collins, Francis (NIH/OD) [E] [mailto (b) (6)

**Sent:** Sunday, February 22, 2015 1:13 AM

To: Perlmutter, Roger M

Cc: Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Jenkins, Christine S.; Smith, Philip

(NIH/NIDDK) [E]; Rodgers, Griffin (NIH/NIDDK) [E]

Subject: Next steps for AMP

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Best, Francis

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From: Collins, Francis (NIH/OD) [E]
Sent: Thu, 26 Mar 2015 19:48:40 +0000

To: Wholley, David (FNIH) [T]
Cc: Wood, Gretchen (NIH/OD) [E]

Subject: RE: Peter Stein " announcement" on AMP EC call

#### Thanks, got it.

From: Wholley, David (FNIH) [T]

Sent: Thursday, March 26, 2015 2:10 PM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Wood, Gretchen (NIH/OD) [E]

Subject: Peter Stein " announcement" on AMP EC call

#### Francis -

Just thinking over tomorrow morning's call it occurred to me that because we had to cancel the January and February AMP EC meetings this will be the first the EC is hearing about the choice of Peter Stein,

(b)(5)

(b) (5) Thanks, David

#### **David Wholley**

Director, Research Partnerships

Foundation for the National Institutes of Health

9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org

Direct (301) 594-6343 | Fax (301) 480-2752

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The hotel is metro accessible as well. 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-- Do not delete or change any of the following text. --

5:30 pm - 6:30 pm Networking Reception

David Wholley (FNIH)

Co-Chairs – John Dunlop (Amgen), Michael Oshinsky (NINDS) 5:15 pm – 5:30 pm Recap and Closing Remarks for Day 1

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## Partnership to Address the Opioid Crisis Face-to-Face Meeting

Bethesda North Marriott Hotel – Salon E 5701 Marinelli Road, Rockville, MD 20852

Tuesday December  $12^{th} - 7:30 \text{ am} - 6:30 \text{ pm}$ Wednesday December  $13^{th} - 7:30 \text{ am} - 4:00 \text{ pm}$ Agenda

# Join WebEx meeting

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

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## December 12th

| 7:30 am – 8:00 am   | Registration and Breakfast                                                                                                      |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------|
| 8:00 am – 8:10 am   | Welcome, Agenda Overview, Meeting Logistics  David Wholley (FNIH)                                                               |
| 8:10 am – 8:30 am   | Welcome and Introduction Francis Collins (NIH), Bill Chin (PhRMA)                                                               |
| 8:30 am – 8:45 am   | Overview of Development of Opioid Use Disorder (OUD) Treatment and Overdose Prevention/Reversal Medications  Nora Volkow (NIDA) |
| 8:45 am – 9:00 am   | Overview of Development of New Pain Medications  Walter Koroshetz (NINDS)                                                       |
| 9:00 am – 12:00 pm  | OUD Treatment and Overdose Prevention/Reversal                                                                                  |
| 9:00 am – 9:15 am   | OUD Working Group<br>Co-Chairs – Osman Ciğeroğlu (Pfizer), Chris Flores (Johnson & Johnson), Jack Stein (NIDA)                  |
| 9:15 am - 10:15 am  | Medication Development Pipeline: Progress, Challenges, and Opportunities  Ivan Montoya (NIDA), David McCann (NIDA)              |
| 10:15 am – 10:30 am | Break                                                                                                                           |
|                     |                                                                                                                                 |

10:30 am - 11:30 am Alternative Outcomes for OUD Medications

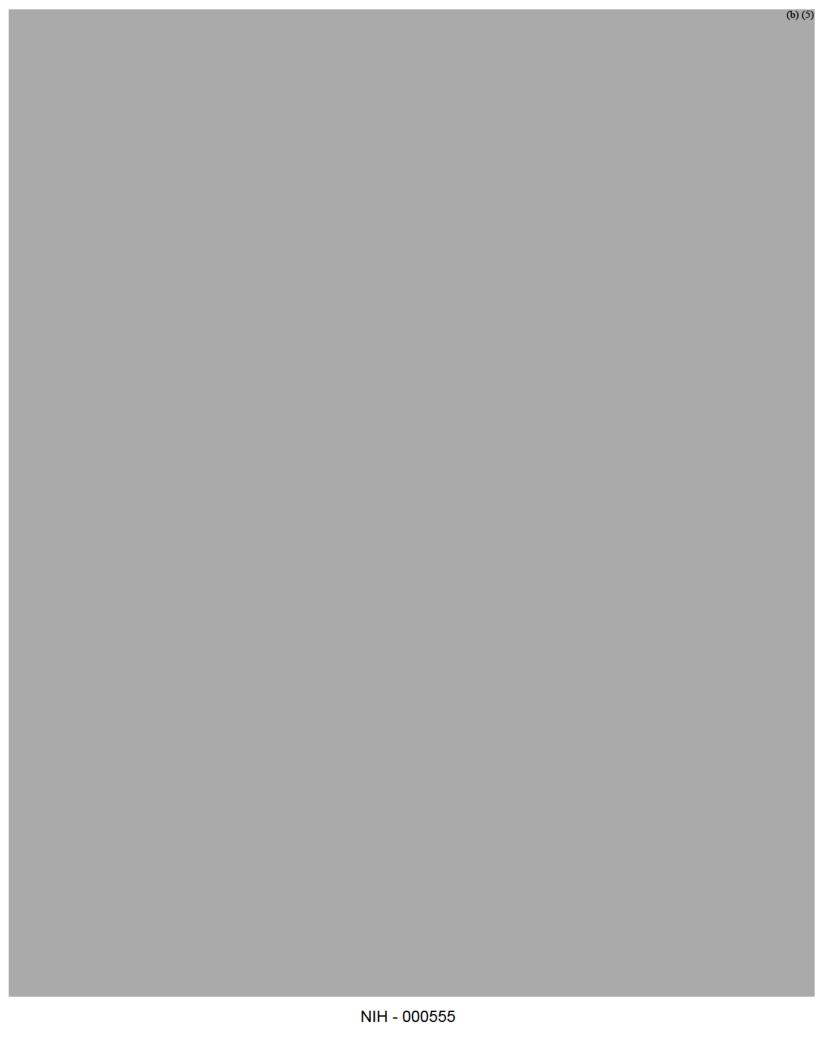
Elena Koustova (NIDA), Tanya Ramey (NIDA)

## Partnership to Address the Opioid Crisis Face-to-Face Meeting

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| 11:30 am – 12:00 pm | Next Steps<br>Nora Volkow (NIDA), Chris Flores (Johnson & Johnson), Osman Ciğeroğlu (Pfizer)        |
|---------------------|-----------------------------------------------------------------------------------------------------|
| 12:00 pm – 1:00 pm  | Lunch                                                                                               |
| 1:00 pm – 5:30 pm   | <b>Development of New Pain Medications Working Groups</b>                                           |
| 1:00 pm – 3:00 pm   | Asset Repurposing Working Group  Co-Chairs – Chris Austin (NCATS), Chris Flores (Johnson & Johnson) |
| 3:00 pm – 3:15 pm   | Break                                                                                               |
| 3:15 pm – 5:15 pm   | Data Sharing Working Group  Co-Chairs – John Dunlop (Amgen), Michael Oshinsky (NINDS)               |
| 5:15 pm – 5:30 pm   | Recap and Closing Remarks for Day 1  David Wholley (FNIH)                                           |
| 5:30 pm – 6:30 pm   | Networking Reception                                                                                |



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## Partnership to Address the Opioid Crisis Face-to-Face Meeting

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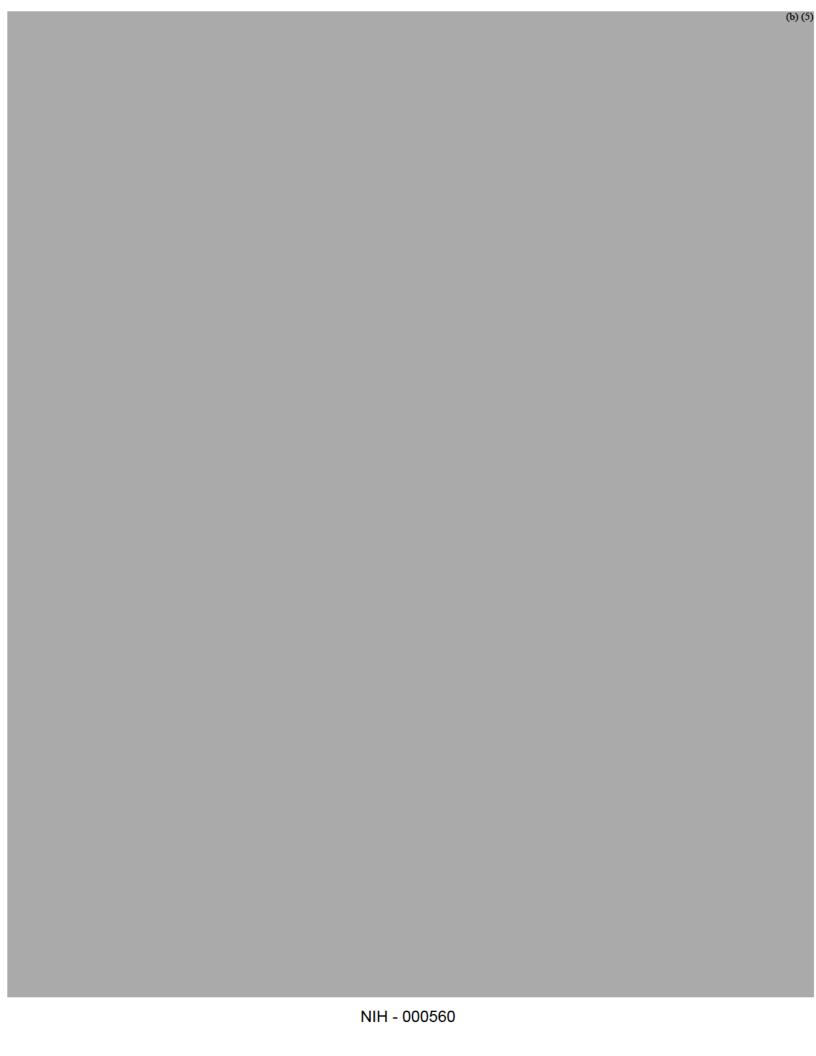
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[E]: Wright, Clinton (NIH/NINDS) [E]: Kehne, John (NIH/NINDS) [E]: Porter, Linda (NIH/NINDS) [E]: Pelleymounter, Mary (NIH/NINDS) [E]: Oshinsky, Michael (NIH/NINDS) [E]: Hachicha, Mohamed (NIH/NINDS)

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Subject: Partnership to Address the Opioids Crisis Face-to-Face Meeting Executive Summary

**Date:** Friday, December 22, 2017 9:06:09 PM

Attachments: Opioid PPP F2F Executive Summary - 12+13Dec2017.pdf

Hi all,

Thank you again for a very productive meeting last week. Please find the executive summary from the meeting attached. We are finalizing more detailed notes and aim to provide those late next week. I hope you all have a very happy holiday.

Best.

Mike

We've moved! Please find our new address below.

**Michael Biarnes** 

Scientific Project Manager

**Foundation for the National Institutes of Health** 

(301) 594-2612

fnih.org

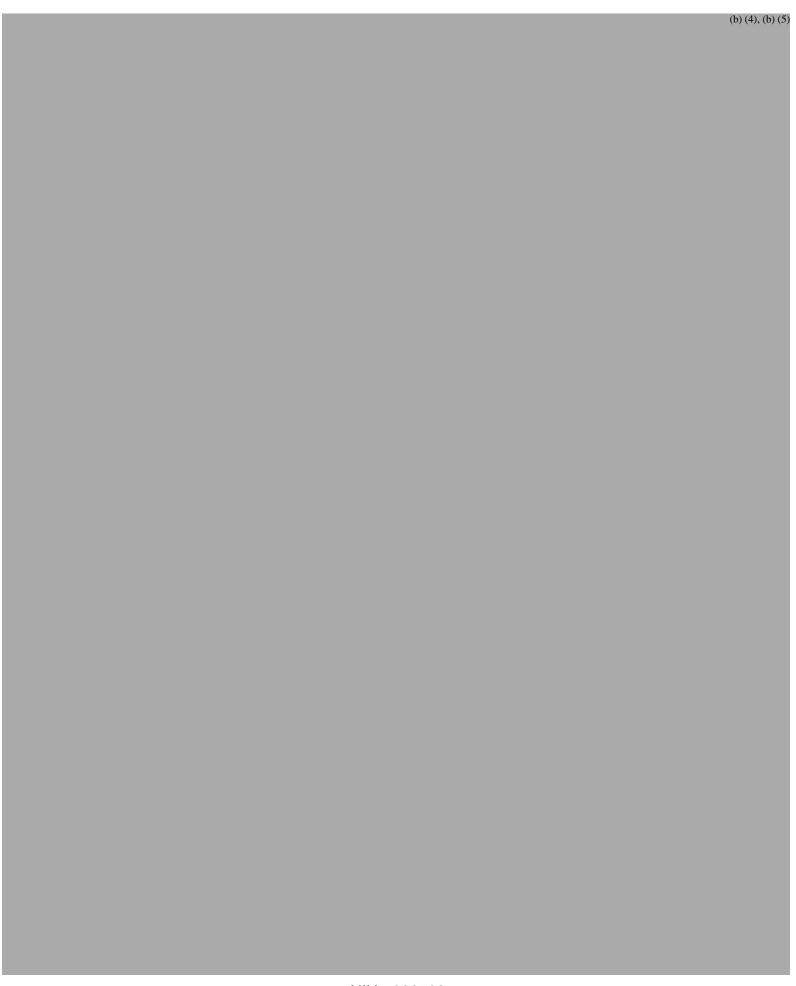
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

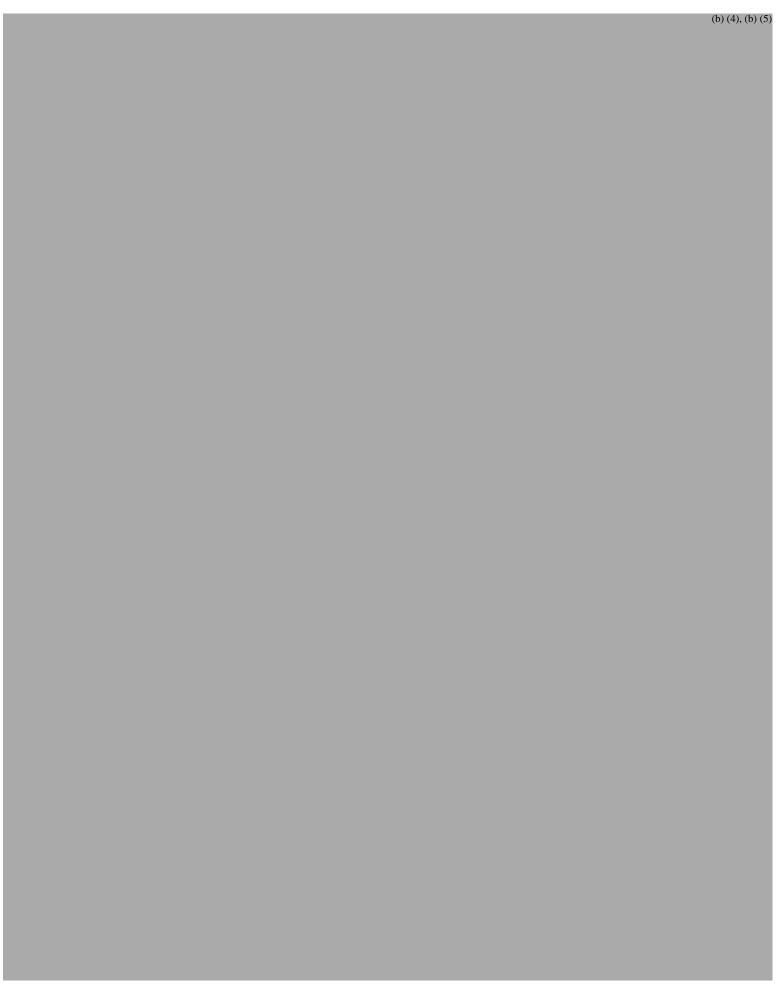
The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from <u>Charity Navigator</u>.

# Partnership to Address the Opioid Crisis Face-to-Face Meeting

December 12–13, 2017 Rockville, Maryland

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From: Thirdwave2

 Sent:
 Thu, 20 Apr 2017 00:46:10 +0000

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Bio companies newt

Sent from my iPhone

Begin forwarded message:

From: Gary Andres < gandres@bio.org> Date: April 19, 2017 at 6:10:54 PM EDT

To: Thirdwave2 < thirdwave2@speakergingrich.com>, "James C. Greenwood"

<igreenwood@bio.org>

Subject: RE: Ending the Opioid Crisis fyi newt

Thanks Newt. We have a couple member companies, including one called Pacira, that have very effective and interesting non-opioid pain relievers. Glad to get you more information about them. We are highlighting their work with the WH too.

----Original Message----

From: Thirdwave2 [mailto:thirdwave2@speakergingrich.com]

Sent: Wednesday, April 19, 2017 5:37 PM

To: Gary Andres <gandres@bio.org>; James C. Greenwood <jgreenwood@bio.org>

Subject: Ending the Opioid Crisis fyi newt

Sigal, Ellen From: Sent: Tue, 25 Oct 2016 20:21:06 +0000 To: aashby@fnih.org;abaruchin@fnih.org;Fauci, Anthony (NIH/NIAID) [E];aginsberg@aeras.org;alleyned@paho.org; (b) (6);Patterson, Amy (NIH/NHLBI) [E];anne;asommer@jhsph.edu;Austin, Christopher (NIH/NCATS) (b) (6); bloomgardenk@ruderfinn.com (b) (6); Burklow, John [E]; (NIH/OD) (b) (6) [E]; (b) (6);choppinp@hhmi.org;ciro.dequadros@sabin. org; Collins, Francis (NIH/OD) [E];ddeferranti@resultsfordevelopment.org;ddopkin@dopkinlaw.com;dick.wilder@Gatesfoundation.org ;doug@SherryLansingFoundation.org;Wholley, David (FNIH) [T];Edison.Liu@jax.org;ef@jhu.edu (b) (6) :espinalm@paho.org:fi (b) (6): Freda. Lewisneberg@nas.edu; Hall;garry@appletreepartners.com;Glass, Roger (NIH/FIC) [E];Grady, Patricia (NIH/NINR) (b) (6); James, Stephanie (FNIH) [T]; Woodcock, Janet (b) (6): (FDA/CDER); jeff allen; Gallin, John (NIH/CC/OD) [E]; jgreenwood; jmarcus@are.com; Mullaney, Janis (NIH/NCATS) [C] (b) (6); john.porter@hoganlovells.com (b) (6); jpalca@npr.org; jperpich@jbsinternational.com;jshaab@umaryland.edu;Tune, Julie (FNIH) [T];Wolf-Rodda, Julie (FNIH) [T];karen.keyes@latonaassociates.com;Hudson, Kathy (NIH/OD) (b) (6);kwright@laskerfoundation.org;lana.skirboll@sanofi.com;Landis, Story (NIH/NINDS) [E];Tabak, Lawrence (NIH/OD) [E];LBrady@drexelmed.edu (b) (6) ;Lowy, Douglas (NIH/NCI) [E] (b) (6) (b) (6);manderson;marty@AMedConsulting.com;Valdez, Mary Lou (FDA/OC);max.coslov@edmondjsafra.org (b) (6);mcgaeryb@od.nih.gov;mdopkin@tyding slaw.com;mforster@umaryland.edu;Gottesman, Michael (NIH/OD) (b) (6) (b) (6); Woolley, Mary (Research [E]; (b) (6); pwalsh@jhmi.edu; Bond, America) Enriqueta; rhimelfarb@stifel.com; Richard.wilder@gatesfoundation.org; Eiss, Robert (NIH/FIC) (b) (6);rouse@rti.org;ryan hohman;sberkley@gavialliance.org;shadary@som.umaryland.edu (b) (6) (b) (6) (b) (6) ;snelson@aaas.org;ssnyder@jhmi.edu;ssterling@spencerstuart.com;sthier@partners.org; (b) (6); vmarquez@iadb.org; (b) (6); Wax, Diane (b);tolchin@gmu.edu (NIH/NIAID) [C]; Wyatt, Richard G (NIH/OD) Subject: FW: The BMJ media query CONFIDENTIAL

This is only the beginning. Ellen

#### Ellen V. Sigal, PhD

Chairperson

Office: (202) 944-6710 Fax: (202) 944-6704



1800 M Street NW - Suite 1050 South - Washington, DC 20036

From: June Wasser [mailto:jwasser@reaganudall.org]

Sent: Tuesday, October 25, 2016 4:03 PM

To: Sigal, Ellen <esigal@sigal.com>; Wise, Courtney <cwise@focr.org>

Subject: FW: The BMJ media query

I was contacted by this reporter and she would also like to talk to you, Ellen. She is writing an article for BMJ on RUF and what we have done since our founding. I gave her a rundown on our current slate of programs. She wants some info on 21<sup>st</sup> Century Cures and I told her you would were more involved than RUF (except for the couple mentions of RUF). I can tell you she focused on 2 things: COI (She claims most of our Board members have conflicts, like Mark with J&J, and I guess even Diana holds some stock). I told her we have a rigorous COI process and members recuse themselves when appropriate. She asked if we ever turned down any money and I said you might know the answer to that but I did not know. She was also interested in IMEDS and talked about the FDAs weakness in tracking drug safety.

From: Sharon Ragland

Sent: Tuesday, October 25, 2016 11:51 AM To: June Wasser < <u>jwasser@reaganudall.org</u>>

Subject: FW: The BMJ media query

As requested. Please advise. Thank you.

Sharon Dixon Ragland
Reagan-Udall Foundation
1025 Connecticut Avenue, NW, Suite 1000
Washington, DC 20036
202-828-1204 – office

From: Comments

**Sent:** Tuesday, October 25, 2016 11:36 AM **To:** Sharon Ragland < <a href="mailto:sragland@reaganudall.org">sragland@reaganudall.org</a>>

Subject: Fw: The BMJ media query

From: Jeanne Lenzer (b) (6)

Sent: Friday, October 21, 2016 4:41 PM

To: Comments

Subject: The BMJ media query

Dear RUF,

I would like to request an interview with Ellen Sigal regarding the work of the Reagan-Udall Foundation. I understand it was founded in response to a 2007 report by the report of the subcommittee on science and technology and I'd like to learn more about the progress since then.

Could we set up a phone interview? I'm writing for The BMJ.

Regards, Jeanne Lenzer

Jeanne Lenzer Associate editor The BMJ

(b) (6) (cell) Skype: jeanne.lenzer jlenzer@bmj.com

Twitter: @JeanneLenzer1

(b) (6)

From: Jennifer Dent

**Sent:** Fri, 30 Dec 2016 14:20:54 +0000 **To:** Collins, Francis (NIH/OD) [E]

Cc: jgreenwood

Subject: RE: BVGH board and happy holidays

Hi Francis,

I will maintain my optimism and continue to believe the Trump team will appoint you to head the NIH again.

I will reach out after life in be settles a bit to see how we might be able to engage you in BVGH's work. Perhaps we can find a time when you, Jim and I can meet in the new year. You and Jim share a common view that cross sector collaborations involving industry can have a real impact on improving global health and building scientific capacity in LMICs.

With very best wishes, Jennifer

Jennifer Dent

President | BIO Ventures for Global Health (BVGH)

1.206.732.2131 office | (b) (6) cell | jdent@bvgh.org | www.bvgh.org

Follow BVGH on Twitter: @BIOVentures



Click here to download BVGH's 2016 Post-BIO International Convention Report

From: Collins, Francis (NIH/OD) [E] [mailto: (b) (6)

Sent: Friday, December 30, 2016 6:03 AM To: Jennifer Dent < jdent@bvgh.org>

Subject: RE: BVGH board and happy holidays

Hi Jennifer,

Thanks for your kind note.

I will leave the NIH Director's position on January 7. It's been a great ride, and I've been deeply gratified by the kind words from Newt and the Congressional Chairs.

Given the current circumstances, it's best that I hold off making any other decisions about Boards. But thanks for your kind invitation, and please keep up the wonderful work of BVGH.

Happy New Year,

Francis

From: Jennifer Dent [mailto:jdent@bvgh.org]
Sent: Wednesday, December 28, 2016 6:58 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: BVGH board and happy holidays

Dear Francis,

I hope this message finds you well and taking some time to enjoy the holidays.

I am counting on President-Elect Trump to make the best decision and appoint you to lead the NIH in years to come. It was encouraging the see Newt Gingrich's positive comments and the support of members of congress. If there is anything Jim Greenwood can do to be helpful please let me know as I know Jim would be pleased to write a letter of support or take any actions that could positively influence the situation in your favor.

BVGH is in the process of recruiting some new board members in order to bring in some fresh new perspectives to our strategy and programs. I realize you are extremely busy but wanted to ask if you would consider joining BVGH's Board of Directors or taking on a special advisory role and participating in one board meeting a year. Currently we hold four meetings a year and each is about four hours long. Most board members join meetings by teleconference and we try to hold one in person meeting a year.

Jim Greenwood, CEO BIO, is our Board Chair and is on the Board Member Selection and Nominating Committee with Jim Geraghty and me. Freda Lewis-Hall is our first new board member. She joined this month and we are in the process of coordinating the announcement with Pfizer. I am thrilled as Freda is an amazing woman and she is passionate about global health and executing impactful programs. We have spoken with Mark Dybul and will reconnect with Mark in September when he is relocated to DC and settled at Georgetown. We are also speaking with a few other potential candidates.

BVGH is working in three strategic areas: R&D for poverty related infectious diseases; capacity building and access to innovative medicines. We plan to launch our African Access Initiative along-side the BIO International Convention next June in San Diego. This access program will initially focus on cancer therapeutics in a few countries and only a few hospitals to start. In January, I will be in Africa to meet with representatives from participating countries including, Prof. Isaac Adewole, Nigeria, Prof. Adoubi (National Cancer Director) Cote d'Ivoire, Cristina Stefan, incoming President, AORTIC and contacts in Kenya. We were planning to visit Dikembe Mutombo's hospital in Kinshasa but given the current circumstances we are postponing that visit. Dikembe's hospital will be one of our pilot sites. Companies have expressed keen interest in developing new business and pricing models in order to enable access to their medicines. I will be pleased to share information as our program plans develop. I will keep the NCI team updated as well.

It would be an honor to have you join the BVGH Board of Directors, or agree to participate in any other capacity, if you are able and if time will permit.

Thank you in advance for your feedback. I look forward to hearing some positive news about the NIH soon!

Warm regards and best wishes for a peaceful and healthy new year.

#### Jennifer

Jennifer Dent
President | BIO Ventures for Global Health (BVGH)

1.206.732.2131 office | (b) (6) cell | jdent@bvgh.org | www.bvgh.org

Follow BVGH on Twitter: @BIOVentures



Click <u>here</u> to download BVGH's 2016 Post-BIO International Convention Report

From: Thirdwave2

**Sent:** Wed, 11 Jan 2017 15:40:54 +0000

To: jgreenwood
Subject: Re: NIH Director

No need

Am told soong is not going to nih newt

Sent from my iPad

```
> On Jan 11, 2017, at 10:21 AM, James C. Greenwood < jgreenwood@bio.org> wrote:
> I'll get back.
> Sent from my iPhone
> On Jan 11, 2017, at 8:48 PM, Thirdwave2 < thirdwave2@speakergingrich.com> wrote:
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> Can your guys quietly go through google etc and see if there are facts i can use to stop him newt
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>>>> Newt

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>>>> Sent from my iPad

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>>>> I'm hearing that Patrick Soon-Shiong is being considered for NIH and that the scientific community would consider that a disaster. Can you get some intel?

>>>>

>>>> Sent from my iPhone

 From:
 Tabak, Lawrence (NIH/OD) [E]

 Sent:
 Wed, 11 Jan 2017 10:50:25 -0500

 To:
 Collins, Francis (NIH/OD) [E]

Subject: RE: NIH Director

(b) (5) All the more reason to focus on what YOU bring to the table which is extraordinary, disruptive, and something he and Nation will be proud of!

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, January 11, 2017 10:47 AM

**To:** Tabak, Lawrence (NIH/OD) [E] **Subject:** Fwd: NIH Director

Sent from my iPhone

Begin forwarded message:

From: Thirdwave2 <thirdwave2@speakergingrich.com>

Date: January 11, 2017 at 10:40:54 AM EST

To: "James C. Greenwood" < jgreenwood@bio.org>

Subject: Re: NIH Director

No need

Am told soong is not going to nih newt

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Sent from my iPad

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Sent from my iPhone

From: Thirdwave2

**Sent:** Sat, 14 Jan 2017 21:15:00 +0000 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: NIH Director

#### Checking newt

Sent from my iPad

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> On Jan 14, 2017, at 3:21 PM, Collins, Francis (NIH/OD) [E]
                                                                             (b) (6) wrote:
> Hi Newt,
> Still waiting for clarity from the Transition Team -- meanwhile, loud alarm bells are going off again. Soon-
Shiong is back on the list, Thiel is apparently pushing him as first choice. Assistance may be needed.
> Francis
> ----Original Message----
> From: Thirdwave2 [mailto:thirdwave2@speakergingrich.com]
> Sent: Wednesday, January 11, 2017 10:41 AM
> To: jgreenwood < jgreenwood@bio.org>
> Subject: Re: NIH Director
> No need
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> Sent from my iPad
>> On Jan 11, 2017, at 10:21 AM, James C. Greenwood < jgreenwood@bio.org > wrote:
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is not respected by scientists.
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Sent:
                         Sun, 15 Jan 2017 21:50:18 +0000
To:
                         Collins, Francis (NIH/OD) [E]
Subject:
                          Re: NIH Director
No
I am pushing on the soong-shiang line
Sent from my iPad
> On Jan 15, 2017, at 4:25 PM, Collins, Francis (NIH/OD) [E]
                                                                            (b) (6) wrote:
> Any news?
> ----Original Message----
> From: Thirdwave2 [mailto:thirdwave2@speakergingrich.com]
> Sent: Saturday, January 14, 2017 4:15 PM
> To: Collins, Francis (NIH/OD) [E]
                                                    (b) (6)
> Subject: Re: NIH Director
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>> Francis
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Thirdwave2

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Collins, Francis (NIH/OD) [E]

Sun, 15 Jan 2017 21:22:30 +0000

From: Sent:

| him. It would be a disaster to have one of the the greatest scientific institution in the world headed by a person who is not respected by scientists.           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| >>>>                                                                                                                                                             |
| >>>> Sent from my iPhone                                                                                                                                         |
| >>>>                                                                                                                                                             |
| >>>> On Jan 11, 2017, at 6:44 PM, Thirdwave2 < thirdwave2@speakergingrich.com> wrote:                                                                            |
| >>>>>                                                                                                                                                            |
| >>>> It is possible                                                                                                                                              |
| >>>>                                                                                                                                                             |
| >>>> What should trump know that would explain disaster Newt                                                                                                     |
| >>>>                                                                                                                                                             |
| >>>> Sent from my iPad                                                                                                                                           |
| >>>>                                                                                                                                                             |
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| >>>>>                                                                                                                                                            |
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| >>>>>                                                                                                                                                            |
| >>>>> Sent from my iPhone                                                                                                                                        |

From: Collins, Francis (NIH/OD) [E] Sent: Wed, 11 Jan 2017 15:43:15 +0000 Thirdwave2 To: Subject: Re: NIH Director Glad to see this, thanks Sent from my iPhone > On Jan 11, 2017, at 10:41 AM, Thirdwave2 < thirdwave2@speakergingrich.com> wrote: > No need > Am told soong is not going to nih newt > Sent from my iPad >> On Jan 11, 2017, at 10:21 AM, James C. Greenwood <i greenwood@bio.org> wrote: >> >> I'll get back. >> >> Sent from my iPhone >>> On Jan 11, 2017, at 8:48 PM, Thirdwave2 < thirdwave2@speakergingrich.com> wrote: >>> >>> I need details >>> Can your guys quietly go through google etc and see if there are facts i can use to stop him newt >>> Sent from my iPad >>>> On Jan 11, 2017, at 8:22 AM, James C. Greenwood < jgreenwood@bio.org > wrote: >>>> I'm told today by a Nobel Laureate in medicine that he doesn't know a single scientist who has any respect for him. It would be a disaster to have one of the the greatest scientific institution in the world headed by a person who is not respected by scientists. >>>> >>>> Sent from my iPhone >>>> On Jan 11, 2017, at 6:44 PM, Thirdwave2 < thirdwave2@speakergingrich.com> wrote: >>>> >>>> It is possible >>>> What should trump know that would explain disaster >>>> Newt >>>>> >>>> Sent from my iPad >>>>>

NIH - 000582

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>>>>

>>>> Sent from my iPhone

From: Wholley, David (FNIH) [T] Sent: 28 Jun 2017 18:05:09 -0400

To:Mark Alles;Collins, Francis (NIH/OD) [E]

Cc:Joel Beetsch;Rupert Vessey;Adam, Stacey (FNIH) [T];Melencio, Cheryl (FNIH) [T]

**Subject:**Re: Partnership for Accelerating Cancer Therapies

That's terrific, and thanks Mark. We will work to set up a time that works for your team, David

Sent from my BlackBerry 10 smartphone.

From: Mark Alles

**Sent:** Wednesday, June 28, 2017 5:57 PM

**To:** Collins, Francis (NIH/OD) [E]

**Cc:** Wholley, David (FNIH) [T]; Joel Beetsch; Rupert Vessey **Subject:** RE: Partnership for Accelerating Cancer Therapies

Great 

we will move quickly and I am excited about how we are thinking about PACT.

Just finished watching your commencement address at SMU in May 2 loved it!

Mark

From: Collins, Francis (NIH/OD) [E] [mailto (b) (6)

**Sent:** Wednesday, June 28, 2017 5:51 PM **To:** Mark Alles <malles@celgene.com>

Cc: Wholley, David (FNIH) [T] < dwholley@fnih.org>; Joel Beetsch < jbeetsch@celgene.com>;

Rupert Vessey <rvessey@celgene.com>

Subject: RE: Partnership for Accelerating Cancer Therapies

That sounds great, Mark. David will be happy to engage with your team after July 4.

Best, Francis

From: Mark Alles [mailto:malles@celgene.com]
Sent: Wednesday, June 28, 2017 5:47 PM

| To: Collins, Francis (NIH/OD) [E] (b) (6)  Cc: Wholley, David (FNIH) [T] < <a href="mailto:dwholley@fnih.org">dwholley@fnih.org</a> ; Joel Beetsch < <a href="mailto:jbeetsch@celgene.com">jbeetsch@celgene.com</a> ; Rupert Vessey < <a href="mailto:rvessey@celgene.com">rvessey@celgene.com</a> > Subject: RE: Partnership for Accelerating Cancer Therapies |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hi Francis,                                                                                                                                                                                                                                                                                                                                                     |
| Thanks for your message and update on the commitment level required to participate.                                                                                                                                                                                                                                                                             |
| First, we apologize for not responding back sooner. In happy to tell you that I met with key members of my team today and we are now very interested in joining this noble effort.                                                                                                                                                                              |
| If acceptable to you and David, we would like to arrange a call for a time shortly after the July 4 <sup>th</sup> holiday to ask a few questions before deciding on next steps.                                                                                                                                                                                 |
| All the best,                                                                                                                                                                                                                                                                                                                                                   |
| Mark                                                                                                                                                                                                                                                                                                                                                            |
| From: Collins, Francis (NIH/OD) [E] [mailto: (b) (6)  Sent: Tuesday, June 27, 2017 3:39 PM  To: Mark Alles <malles@celgene.com> Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org> Subject: Re: Partnership for Accelerating Cancer Therapies</dwholley@fnih.org></malles@celgene.com>                                                                           |
| Hi Mark,                                                                                                                                                                                                                                                                                                                                                        |

In following up my message from May 6 (copied below) to see whether Celgene is interested in taking part in PACT. Since that message, I am glad to report that we have found ways to

reduce the needed commitment per company to (b) (4), while sustaining the most critical part of the research plan. I am also happy to tell you that the White House has taken a strong interest in this project and is considering convening the group of participating companies for a significant Presidential event in July.

It would be terrific to have Celgene as a partner in this unprecedented effort. David Wholley of the Foundation for NIH (cc2d here) stands ready to answer any questions you might have about the current plan. Please let me know your thoughts.

Best, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, May 06, 2017 7:13 AM

To: malles@celgene.com

**Cc:** Wholley, David (FNIH) [T] < <a href="mailto:dwholley@fnih.org">dwholley@fnih.org</a> **Subject:** Partnership for Accelerating Cancer Therapies

Dear Mark:

It was a pleasure to meet you at the Milken LA meeting, and In glad we got a chance to talk about the Partnership for Accelerating Cancer Therapies (PACT), which we have been developing with multiple pharmaceutical companies and FDA over the last eight months or so. As we discussed, PACT is focused on the critical issue of developing better biomarkers for selecting and testing cancer immunotherapies and relevant combinations. Following up your request for more information, I have attached a text executive summary and a slide deck overviewing the partnership, as well as the full text of the white paper that contains the initial research plan for those who may need more detail.

In very glad to hear you may be interested in having Celgene consider joining PACT. We are looking to determine a final set of committed partners by the end of June, with the plan to reconvene them thereafter along with our FDA colleagues to work out the final research plan in more detail, so there is still ample room for input here from Celgene should you decide to participate. If you or any of your colleagues want to follow up on the financial implications of participation or indeed any aspect of PACT would ask that you contact David Wholley (copied)

at the Foundation for the NIH, who have been overseeing the project development and fundraising aspects of this.

All the best, Francis

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

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From: Engelman, Jeffrey

To: <u>Collins, Francis (NIH/OD) [E]</u>

Cc: Doroshow, James (NIH/NCI) [E]; Lowy, Douglas (NIH/NCI) [E]; Bradner, James; Cho, Jessica

Subject: PACT update and working group process

Date: Monday, August 8, 2016 5:04:16 PM

Dear Dr. Collins,

Jay passed along your kind invitation to serve as the industry co-chair for the PACT initiative focused on combination clinical trials. I think this sounds very exciting and it would be extremely gratifying to make substantial progress in this area. I wholeheartedly accept your invitation.

I look forward to hearing next steps and working with the NIH on these important initiative.

All the best, Jeff

# Jeffrey Engelman, M.D., Ph.D.

Global Head of Oncology Novartis Institutes for BioMedical Research

Sent: Thursday, July 28, 2016 11:11 PM

To: 'James.bradner@novartis.com'

**Cc:** Hudson, Kathy (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Wholley, David (FNIH) [T]; Adam, Stacey (FNIH) [T]; Rosema, Laura (NIH/OD) [E]; Baker, Rebecca

(NIH/OD) [E]

Subject: PACT update and working group process

Dear Jay,

Thanks again for your words of support and enthusiasm for our partnership efforts at the New Democrats luncheon. I wanted to update you on some significant progress we've made on the Partnership for Accelerating Cancer Therapies (PACT), and to ask if Jeff Engelman could play a key leadership role in the effort.

The Vice-President cited PACT from the podium at the White House Cancer Moonshot Summit on June 29<sup>th</sup> as one of the more exciting opportunities in the Moonshot. After extensive conversations with potential partners and stakeholders, we've selected two focus areas for PACT:

# 1. Identification and validation of biomarkers for the response to cancer therapies

### 2. Establishment of a platform for combination clinical trials

We believe these areas will address the most pressing current needs in the immuno-oncology field, and are uniquely suited for a pre-competitive research collaboration.

Given the excitement and momentum generated by the Moonshot, we're eager to move PACT into the next phase of development, which involves convening a "Working Group" of experts from NCI, industry, patient groups, and academia to agree on a suitable research plan. From our experience with AMP, we intend to select one industry scientist and one NCI representative to co-chair the Working Group. Both Doug Lowy and Jim Doroshow of NCI enthusiastically recommended Jeff to serve as the industry co-chair for focus area #2 in combination clinical trials.

The time commitment for Jeff would entail 3 teleconferences (a couple of hours each) and at least

one in-person 2-day meeting in the early fall, with the key deliverable a white paper describing the consensus of the group on a common mission and a high level plan. Others from the Novartis Oncology group could also aid in the development of a detailed plan once the white paper is completed. Given how fast the field is moving, we'd like to solidify a plan and gather the necessary funding commitments by the end of this year, with a view to launching an effort in early 2017. We are engaging the Foundation for the NIH to manage this effort, and Jeff would be fully staffed by FNIH to make this successful.

Would you be willing to consider Jeff in this role? I will be out of the country next week, but David Wholley at FNIH (copied) can answer any detailed questions about the process, and I am happy to speak when I return on August 9<sup>th</sup>.

Best personal regards,

Francis

**From:**sawyersc@mskcc.org **Sent:**27 Jan 2016 18:17:35 -0500

To:Collins, Francis (NIH/OD) [E];Lowy, Douglas (NIH/NCI) [E];Staudt, Louis (NIH/NCI) [E]

**Cc:**rachel.liao@genomicsandhealth.org;Haussler, David;Hudson, Tom

Subject:invitation to GA4GH data sharing workshop on Friday April 15th at AACR (New Orleans)

Attachments: ACGI Exec Summary 2016-01-27.docx

Dear Francis, Doug and Lou,

I am writing on behalf of Global Alliance for Genomics and Health (GA4GH) to alert you to a cancer data-sharing workshop that we are hosting on April 15, 2016 in New Orleans, immediately preceding the AACR 2016 annual meeting. In light of Vice President Biden srecent remarks emphasizing data sharing, this is a timely opportunity to have a serious discussion about how to leverage and expand several ongoing data sharing efforts. It would be great if one or more of you could be present to represent the views of NIH/NCI.

Based on conversations with a range of stakeholders, we have converged on a pilot project called the Actionable Cancer Genome Initiative (ACGI), with the goal of sharing somatic cancer genomic and clinical data on five targetable cancer genes for which there is an urgent need for clarity on rare variants (EGFR, ERBB2, BRAF, BRCA1, BRCA2). Several institutions including Memorial Sloan Kettering Cancer Center, Dana-Farber Cancer Institute, Princess Margaret Cancer Centre, and Gustave Roussy (all through the AACR-GENIE initiative) have agreed to kick start the effort by sharing their data. We have hearing great interest from other group as well.

We expect ~70 people representing a large repertoire of groups with relevant cancer clinical data and expertise to participate. I have attached a draft document that lays out some of this in more detail. Other members of the planning committee are listed below.

Please let Rachel Liao and me know asap if you can attend. We would love to include your name(s) in the invitations to other participants!

Sorry for the rush but the VP has issued a call for action!

Best,

| on behalf of the planning committee:           |
|------------------------------------------------|
| Fabien Calvo                                   |
| Tom Hudson                                     |
| Mark Lawler                                    |
| Nuria Lopez Bigas                              |
| Julia Wilson                                   |
|                                                |
|                                                |
| Charles L. Sawyers, M.D.                       |
| Investigator, Howard Hughes Medical Institute  |
| Chair, Human Oncology and Pathogenesis Program |
| Marie-Jose and Henry Kravis Professor          |
| Memorial Sloan Kettering Cancer Center         |
| 1275 York Avenue                               |
| New York, NY 10065                             |
| 646-888-2138                                   |
| sawyersc@mskcc.org                             |
|                                                |
|                                                |

Charles

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# Porter, Kevin (NIH/OD) [E]

**From:** sawyersc@mskcc.org

Sent: Thursday, August 18, 2016 9:13 PM

To: Ivy, Percy (NIH/NCI) [E]

Cc: Collins, Francis (NIH/OD) [E]; Lowy, Douglas (NIH/NCl) [E]; Doroshow, James (NIH/NCl) [E]; Wholley,

David (FNIH) [T]; Adam, Stacey (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; Rosema, Laura (NIH/OD) [E];

jeffrey.engelman@novartis.com

**Subject:** RE: ATTN RESPONSE REQUESTED/TIME-SENSITIVE: Vice President's Cancer Moonshot Initiative:

Invitation to participate in PACT Workgroup - Focus Area #2

Follow Up Flag: Follow up Flag Status: Completed

# Dear Percy (and Jeff),

There are critical issues of obvious importance. I am honored to be invited and happy to help with PACT. As some of you know, I am also on the Blue Ribbon Panel for the cancer moonshot and serve on the NCAB, so I am quite familiar with all these topics.

Can I assume these are not conflicting responsibilities? (other than the time commitment!)

Best regards,

### Charles

```
From: Ivy, Percy (NIH/NCI) [E] [mailto (b) (6)

Sent: Wednesday, August 17, 2016 8:22 PM

To: Sawyers, Charles/HOPP <sawyersc@mskcc.org>
Cc: Collins, Francis (NIH/OD) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); 'Engelman, Jeffrey' <jeffrey.engelman@novartis.com>; Ivy, Percy (NIH/NCI) [E]
```

Subject: ATTN RESPONSE REQUESTED/TIME-SENSITIVE: Vice President's Cancer Moonshot Initiative: Invitation to

participate in PACT Workgroup - Focus Area #2

Importance: High

### Dear Dr. Sawyers:

We are contacting you on behalf of Francis Collins, Director of the National Institutes of Health (NIH); Doug Lowy, Acting Director of the National Cancer Institute (NCI); Jim Doroshow, Acting Director for Clinical and Translational Research at NCI; and leaders in the biopharmaceutical industry to ask for your assistance with a new public-private-partnership (PPP) in immuno-oncology being formed as part of the Vice President's Cancer Moonshot Initiative. This initiative, called the Partnership for Accelerating Cancer Therapies (PACT), has arisen from several months of discussions between NIH, industry, and cancer patient organizations and was cited by the Vice-President of the United States during the White House Cancer Moonshot Summit on June 29<sup>th</sup>, 2016 as a particularly promising example of boundary-breaking collaborative research.

From: <u>Bradner, James</u>

To: Collins, Francis (NIH/OD) [E]

Cc: Neville, Frances

Subject: 9/28

Date: Wednesday, September 20, 2017 11:32:43 PM

Francis. Thank you for the invitation to join this important discussion next Thursday evening in DC. I would like very much to join, contribute. Whenever convenient, could you or a colleague kindly confirm, and share details regarding time/place so that we can make all needed arrangements on our end? Needless to say, there is no need to help with travel arrangements, just advice on timing. Thank you, again, for the invitation. I am so hopeful to be of service to your mission, to science. Best - Jay

--

## Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research james.bradner[at]novartis.com

From: <u>Bradner, James</u>

To: Collins, Francis (NIH/OD) [E]

Subject: Congress

**Date:** Friday, July 8, 2016 6:46:45 AM

Francis, I so enjoyed seeing you in Washington this week. I recognize this was not your first rodeo, but it was both fascinating and enjoyable to watch you in action - educating, advocating. Thank you for your generous words. I will always be available to help you, and the NIH, defend the need for augmented research funding from the US Government. Please let me know if/when I can help. Best – Jay

## James E. Bradner, MD

President | Novartis Institutes of BioMedical Research 181 Massachusetts Avenue Cambridge, MA 02139

Executive Assistant
Frances Neville
(617) 871-3028
frances.neville@novartis.com

From: Bradner, James

To: <u>Collins, Francis (NIH/OD) [E]</u>

Cc: Rammohan, Revathi; Brown, Scott; Engelman, Jeffrey; Hammerman, Peter; Dranoff, Glenn; Petruzzelli, Lilli;

Lockwood, Jeffrey

Subject: PACT

Date: Thursday, October 5, 2017 9:59:27 AM

#### francis.

thank you for the invitation to steer and now join the NIH-PACT program focused on cancer immunotherapy biomarker discovery. this week we assembled our cancer and institutional leadership (many cc'd here), to examine the clarified design principles emerging from the workstream and to assess alignment with our critical path in IO and cancer medicine. we applaud the effort to pull together so many leading institutions and scientists around this generational activity. we agree violently that the development of next-generation IO agents will require new measurements guiding use and explaining (in)activity. in this regard, we are well aligned with the program and would like to participate.

my sense is that there are important strategic details still to define, regarding scientific focus, institutions/scientific leaders involved, clarified and prioritized measurements. jeff, peter, glenn and lilli cc'd will surely have helpful guidance, should the PACT welcome insights at this pivotal stage. candidly, our principal interest remains connected to the safe harbor the PACT might provide for combination clinical trials of next-gen agents between companies. we would welcome a chance to work with peer institutions through the NIH network. but even with a focus on biomarker creation, curation and deployment, we are motivated to join. i defer to jeff to provide guidance as to how best and who best to contribute these and other guidance.

finally, we are working hard to help you hit your deadling on the appeursement and would like to be

finally, we are working hard to help you hit your deadline on the announcement and would like to be a party to the announcement. peter can join in DC at the national press club, if this invitation is still open and helpful.

thank you for the invitation, again, to join. we so admire the heroic work you continue to lead, orienting our government around this rarified moment in biomedicine, openly assembling diverse research communities, and always defending basic research. please advise on next steps.

.

best - jay

--

# Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research james.bradner[at]novartis.com

From: <u>Bradner, James</u>

To: Collins, Francis (NIH/OD) [E]

Subject: price

Date: Friday, September 29, 2017 4:49:18 PM

Attachments: price tweets.png

francis. i just saw this tweet a minute ago, and hope that this does not derail your important discussions. the news makes dinner last evening even that much more interesting. it was a pleasure and honor to participate. best - jay

--

# Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research james.bradner[at]novartis.com

# The Associated Press (@AP)

BREAKING: Health and Human Services Secretary Tom Price resigns amid criticism of his travel on private planes.

# BBC Breaking News (@BBCBreaking)

US health secretary Tom Price quits after it emerged he took private planes at taxpayers' expense bbc.in/2ydZk3z From: Bradner, James

To: <u>Collins, Francis (NIH/OD) [E]</u>
Subject: Re: A rather important request

**Date:** Monday, September 18, 2017 7:28:35 PM

francis, thank you. i just tried you by phone but it did not connect. i am traveling back from and the reception issue could well be on my end. i will try again from the next location. thanks again, jay

ps. NIBR CFO and Engelman meeting this week on PACT, thank you for the specifics!

# Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research james.bradner[at]novartis.com

On Sep 19, 2017, at 7:21 AM, Collins, Francis (NIH/OD) [E] (b) (6) wrote: Hi Jay,

Might you have a couple of minutes to call me this evening? (b) (6)

This is actually not about PACT, though we continue to look forward to a positive response from Novartis on that. ©

Francis

From: Bradner, James

To: <u>Collins, Francis (NIH/OD) [E]</u>

**Subject:** Re: Meeting invitation on public-private partnerships--September 11, 2017

**Date:** Sunday, August 20, 2017 11:04:07 AM

francis, thank you for this invitation. I have taken meetings this week on precisely this subject. many on our leadership team are galvanized by this pressing generational challenge. regrettably, our research leadership are collecting in basel on 9/12. vas and i will find a designate for the planning call. please advise if we can send our assignee to the event on the 11th, and we will do this. thanks so much for appraising us of this important and exciting initiative. best - jay

--

### Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research james.bradner[at]novartis.com

**From:** "Collins, Francis (NIH/OD) [E]"

Date: Friday, August 18, 2017 at 5:23 PM

To: "garnett\_tim@lilly.com", "lundberg\_jan@lilly.com", Andrew Plump,

"Michael.severino@abbvie.com", "rob.scott@abbvie.com", "sharper@amgen.com",

"peisenbe@amgen.com", "Bernhardt.zelher@astellas.com", "keenang@MedImmune.com",

"Andreas.busch@bayer.com", "joerg.moeller@bayer.com", "Alfred.sandrock@biogen.com",

"clive.wood@boehringer-ingelheim.com", "sabine.luik@boehringer-ingelheim.com",

"Thomas.Lynch@bms.com", "rvessey@celgene.com", "ggormley@dsi.com",

"lynn\_kramer@eisai.com", "Luciano.rossetti@emdserono.com", Patrick Vallance,

"william.r.sigmund@gsk.com", "amaree@its.jnj.com", "DWMS@lundbeck.com",

"roger.perlmutter@merck.com", Vas Narasimhan, "Aradhye, Shreeram",

 $"ALNM@novonordisk.com"\ , "raymond.sanchez@otsuka-us.com"\ , "mikael.dolsten@pfizer.com"\ ,$ 

"elias.zerhouni@sanofi-aventis.com", "antony.loebel@sunovion.com",

"michael.hayden@teva.co.il", "PStoffe4@its.jnj.com", "jallalb@medimmune.com",

"horning.sandra@gene.com", James Bradner, "David.Nicholson@Allergan.com",

"john.orloff@alexion.com", "Alan.Dunton@pharma.com", "chin@phrma.org"

Cc: "Wolinetz, Carrie (NIH/OD) [E]", "Bill Chin (chin@phrma.org)"

**Subject:** Meeting invitation on public-private partnerships--September 11, 2017

# Dear BMAC and Hever Group Members, and other PhRMA R&D Leaders,

We invite you to join us in a discussion on <u>September 11, 2017</u> [3:30—5 PM EDT] to decide on the next steps in the development of a public-private partnership opportunity with NIH and FDA, which will focus on accelerated research and development efforts that can lead to approval of potent but non-addictive analgesics – as a critically-needed alternative to traditional opioids. We hope that you can free your schedule to attend in person at the PhRMA offices in Washington, D.C. for this 90 minute discussion and decision-making session. A teleconference option will also be available.

This meeting follows up on the discussion about the need and opportunity for such a partnership held at the April Hever meeting, which in turn led to three NIH-sponsored cutting-edge scientific workshops. These brought together innovative experts from government, academia, and industry, including representatives from several of your companies.

In order to have a proposed plan to consider for the September 11 BMAC meeting, we are asking you to nominate a senior member of your team, preferably in neuroscience and/or pain research, to join a preparatory teleconference on September 7, 2017 [time to be determined]. The purpose of this call is to help refine a proposal for research in this space for consideration by R&D leaders the following week. We anticipate this project could involve: developing biomarkers to identify subsets of patients with varying responses to pain treatments; establishing a data and information sharing collaborative between industry groups, with NIH serving as an honest broker; to learn from common efforts and accelerate late stage compounds; development of an objective nociometer (a "pain-o-meter") for pain assessment and response to interventions that will empower patients and facilitate the testing of new drugs; working with FDA to accelerate development and review of novel analgesics; and access to a NIH-sponsored clinical research network.

Shortly after the September 11<sup>th</sup> discussion, Governor Chris Christie, who is leading the President's Commission on Combatting Drug Addiction and the Opioid Crisis, is planning to convene pharmaceutical company CEOs in Trenton or Philadelphia to enlist their help in the government-wide effort to address this national emergency. Such a meeting, which will also involve NIH and FDA leadership, would seem to provide an opportune time to promote the development of a partnership.

We recognize the tight timeline for this request, but the sense of urgency to make rapid progress in the face of the current expanding epidemic cannot be overemphasized. We hope you will join with NIH and FDA in developing a workplan for a successful partnership to move forward. Please let us know: 1) if you will be able to attend the September 11<sup>th</sup> meeting; and 2) whom you would like to nominate to participate in the September 7<sup>th</sup> planning call.

With best personal regards,

Francis S. Collins, M.D., PhD. and William W. Chin, M.D.

From: <u>Bradner, James</u>

To: Collins, Francis (NIH/OD) [E]

**Subject:** Re: Opioid Use Disorders Private Public Partnership

**Date:** Friday, April 21, 2017 7:39:19 AM

Thanks, Francis. I hope and trust all is well in DC. On behalf of scientists everywhere thanks also for fighting the good fight! Jay

On Apr 21, 2017, at 6:04 AM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

## Many thanks!

**From:** Dolmetsch, Ricardo [mailto:ricardo.dolmetsch@novartis.com]

**Sent:** Friday, April 21, 2017 12:24 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

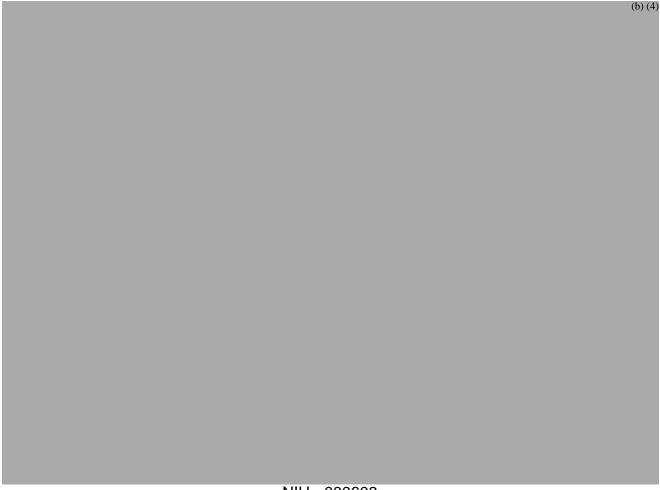
Cc: Bradner, James < <u>james.bradner@novartis.com</u>>; Narasimhan, Vas

<vas.narasimhan@novartis.com>; Bar Zohar, Danny <danny.bar\_zohar@novartis.com>

Subject: Opioid Use Disorders Private Public Partnership

Dear Dr. Collins,

I am the Global Head of Neuroscience at NIBR, the early research and development branch of Novartis. Jay Bradner and Vas Narasimhan have asked me to write to you about engaging in a public private partnership to address opioid use disorders. We have a long standing interest in pain and addiction and I would be glad to provide any help that I can. I'm providing some answers to your questions below:



Suggestion from your company:
Suggestion from another Hever company:
Perhaps this person could emerge from the second meeting.
I hope this is helpful.
Warm regards,
Ricardo

Ricardo Dolmetsch VP and Global Head of Neuroscience Novartis Institutes for Biomedical Research Adj. Professor of Neurobiology Stanford University School of Medicine

# Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research james.bradner[at]novartis.com

From: Bradner, James

To: <u>Collins, Francis (NIH/OD) [E]</u>

Cc: Wholley, David (FNIH) [T]; Engelman, Jeffrey; Brown, Scott; Rammohan, Revathi

**Subject:** Re: PACT and Novartis

**Date:** Sunday, September 10, 2017 9:55:49 AM

Thank you, Francis. I remain enthusiastic about PACT. I am cc'ing Jeff Engelman, Scott Brown (GC/CAO) and Revathi Rammohan (CFO) to advise. If not already in-hand, to sign on we will need a sense of the scope of research and commitment. Is there a proposal as yet emerging from the working group? Best - Jay

--

### Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research james.bradner[at]novartis.com

From: "Collins, Francis (NIH/OD) [E]"

Date: Saturday, September 9, 2017 at 5:08 PM

**To:** James Bradner

**Cc:** "Wholley, David (FNIH) [T]" **Subject:** PACT and Novartis

Hi Jay,

Just checking back with you about Novartis's willingness to join the Partnership for Advancing Cancer Therapies (PACT). When you and I spoke on July 13, you thought this would almost certainly be a positive response, but there were apparently still some internal steps by you and Jeff Engelman to reach approval. I had the impression that this wouldn't take very long, but I'm sure everyone has a lot on their plate.

We now have seven big pharmas signed on, and two more are seriously considering and planning to respond in the next few days – so if Novartis joins that could make ten! We are hoping to make an announcement in another week or two. It would be great to hear a definite Novartis yes.

Many thanks, Francis

From: <u>Bradner, James</u>

To: <u>Collins, Francis (NIH/OD) [E]</u>

Subject: Re: PACT update and working group process

Date: Monday, August 8, 2016 12:02:37 PM

francis, thank you for the note and hello from sunny nantucket. jeff would be perfectly suited to this role - please do reach out! jay

### Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research james.bradner[at]novartis.com

From: "Collins, Francis (NIH/OD) [E]"

Date: Monday, August 8, 2016 at 11:56 AM

To: "Bradner, James"

**Cc:** "Hudson, Kathy (NIH/OD) [E]" , "Lowy, Douglas (NIH/NCI) [E]" , James Doroshow , "Wholley, David (FNIH) [T]" , "Adam, Stacey (FNIH) [T]" , "Rosema, Laura (NIH/OD) [E]" , "Baker, Rebecca (NIH/OD)

[E]'

Subject: RE: PACT update and working group process

Hey there Jay,

We're hoping to get this working group underway quickly – is it OK for us to ask Jeff Engelman to help? See below.

### Thanks, Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, July 28, 2016 11:11 PM
To: 'James.bradner@novartis.com'

**Cc:** Hudson, Kathy (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Wholley, David (FNIH) [T]; Adam, Stacey (FNIH) [T]; Rosema, Laura (NIH/OD) [E]; Baker, Rebecca

(NIH/OD) [E]

**Subject:** PACT update and working group process

Dear Jay,

Thanks again for your words of support and enthusiasm for our partnership efforts at the New Democrats luncheon. I wanted to update you on some significant progress we've made on the Partnership for Accelerating Cancer Therapies (PACT), and to ask if Jeff Engelman could play a key leadership role in the effort.

The Vice-President cited PACT from the podium at the White House Cancer Moonshot Summit on June 29<sup>th</sup> as one of the more exciting opportunities in the Moonshot. After extensive conversations with potential partners and stakeholders, we've selected two focus areas for PACT:

- 1. Identification and validation of biomarkers for the response to cancer therapies
- 2. Establishment of a platform for combination clinical trials

We believe these areas will address the most pressing current needs in the immuno-oncology field, and are uniquely suited for a pre-competitive research collaboration.

Given the excitement and momentum generated by the Moonshot, we're eager to move PACT into the next phase of development, which involves convening a "Working Group" of experts from NCI, industry, patient groups, and academia to agree on a suitable research plan. From our experience with AMP, we intend to select one industry scientist and one NCI representative to co-chair the

Working Group. Both Doug Lowy and Jim Doroshow of NCI enthusiastically recommended Jeff to serve as the industry co-chair for focus area #2 in combination clinical trials.

The time commitment for Jeff would entail 3 teleconferences (a couple of hours each) and at least one in-person 2-day meeting in the early fall, with the key deliverable a white paper describing the consensus of the group on a common mission and a high level plan. Others from the Novartis Oncology group could also aid in the development of a detailed plan once the white paper is completed. Given how fast the field is moving, we'd like to solidify a plan and gather the necessary funding commitments by the end of this year, with a view to launching an effort in early 2017. We are engaging the Foundation for the NIH to manage this effort, and Jeff would be fully staffed by FNIH to make this successful.

Would you be willing to consider Jeff in this role? I will be out of the country next week, but David Wholley at FNIH (copied) can answer any detailed questions about the process, and I am happy to speak when I return on August 9<sup>th</sup>.

Best personal regards,

Francis

From: Bradner, James

To: Collins, Francis (NIH/OD) [E]
Cc: Craig Thompson MD

Subject: The Fragile State of the Midwest's Public Universities - The Atlantic

**Date:** Tuesday, October 17, 2017 2:17:29 AM

francis. certain you saw this outstanding piece in the atlantic. fight fight fight. fondly, jay

 $\underline{https://www.theatlantic.com/business/archive/2017/10/midwestern-public-research-universities-funding/542889/}$ 

# Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research james.bradner[at]novartis.com

As a result of preliminary discussions among the parties, the partnership has decided to focus on two key precompetitive research challenges in immuno-oncology (I/O):

- 1. Identification and validation of biomarkers for response and resistance to cancer immunotherapies
- 2. Establishment of a platform for selecting and testing combination therapies

We, Jeff and I, have been asked by Doug Lowy, Acting Director of the NCI; Jim Doroshow, Acting Director for Clinical and Translational Research; and Jay Bradner, President of the Novartis Institutes for BioMedical Research, to head a Technical Working Group to further develop the design for a partnership around the second focus area (platform for selecting and testing combination therapies). The Working Group will include scientists from NCI, 8-10 pharmaceutical companies, and key academic experts. We felt your perspective would be particularly valuable in Focus Area #2, and are asking if you would consider joining the Working Group to participate in the design effort for PACT.

The main focus of the design effort is to produce a "whitepaper" that outlines the key challenges in selecting and testing combination therapies and to define and prioritize the most effective potential solutions that a public-private research collaboration should tackle. Our hope would be that the resulting document would include approximate timelines and milestones, and enable potential funders to make at least initial decisions on whether to move forward or not with an investment in PACT. If industry interest in funding successful, we would recuse any academic participants from the second phase in order to avoid any conflicts of interest regarding future NIH grants, and convene instead a smaller group consisting of NIH and interested private sector partners to create a final work plan with detailed logistics, budgets, and milestones.

The development of a plan for PACT is being carried out in close coordination with the work of the Moonshot Blue Ribbon Panel, which will report its recommendations about NCI/NIH investments in cancer research at the NCAB meeting in early September. PACT represents a complementary effort that seeks to engage closely with our pharmaceutical partners.

Our goal is to launch PACT in mid-2017. The process follows a similar path to that used very successfully in building other public-private biomedical research partnerships between NIH and industry, notably the Accelerating Medicines Partnership: https://www.nih.gov/research-training/accelerating-medicines-partnership-amp.

We estimate that Working Group members will be required to participate in 3-4 teleconferences (~2 hours each) and 2 in-person meetings (~1.5 days each) beginning in late August and concluding in November, and may be asked to assist in writing specific sections of the whitepaper. The costs of reasonable travel to and from the in-person meetings will be covered for academic participants.

Dr. Collins has asked the Foundation for the National Institutes of Health (FNIH) to manage the design and launch of PACT. If you agree to join our Working Group, our colleague at FNIH, Stacey Adam, will be reaching out to you to orient you further and organize the relevant teleconferences and in-person meetings. Stacey will be happy to answer any additional questions you may have about the process.

We are very enthusiastic about PACT, and the prospect of working with you on this exciting and innovative initiative. So that we may move forward expeditiously, we ask that you please let us know if you are interested in participating on the Working Group no later than Friday, August 19. Thank you.

Kind regards,

Percy Ivy, M.D.

Associate Branch Chief, Investigational Drug Branch Cancer Therapy Evaluation Program (CTEP) National Cancer Institute (NCI)

Jeffery Engelman, M.D., Ph.D. Vice President and Global Head of Oncology Novartis Institutes for BioMedical Research

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Please note that this e-mail and any files transmitted from Memorial Sloan Kettering Cancer Center may be privileged, confidential, and protected from disclosure under applicable law. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any reading, dissemination, distribution, copying, or other use of this communication or any of its attachments is strictly prohibited. If you have received this communication in error, please notify the sender immediately by replying to this message and deleting this message, any attachments, and all copies and backups from your computer.

**Sent:** Tue, 27 Sep 2016 13:23:05 -0400 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** Automatic reply: BMGF, Pfizer, AMP, PACT

Thank you for your message. I am on travel until October 1 with limited access to e-mail. For urgent matters, please contact Ms. Liz Johns at ejohns@fnih.org.

 Sent:
 Sat, 24 Sep 2016 07:06:51 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Cc: Steve Paul

Subject: BMGF, Pfizer, AMP, PACT

## Confidential

Good morning, Francis. It was good to see you at Ellen's celebration - of course, everyone loved the song! A few vignettes:

First, we wanted to let you know, confidentially, that the BMGF and Pfizer have won the first Charles Sanders Partnership Awards, which we will bestow the evening of October 19th, following the symposium at NIH. We are working with Trevor and Freda to orchestrate who will come. These are on your calendar. Any chance we can get a song too - either at the symposium or at dinner?

On another note - thanks for your help on the AMP call yesterday. Much, much appreciated! The PACT meeting went well too - Stacey and David are awesome. Doug, Jim and Dinah were there so we got the NCI top brass. Good discussion, random at first and then coalesced into action items. I know David will soon or has brought you up to date on this.

Have a good weekend! M.

Sent:Tue, 11 Oct 2016 16:44:45 -0400To:Collins, Francis (NIH/OD) [E]Subject:Buffy and the Kennedy Center

Hi Francis,

I had a good conversation with Buffy re: Kennedy Center. She found the concept very interesting but had a bunch of semi-technical questions I could not answer. I am sure you know the answers. FYI, she has just made some donations (including underwriting Renee Fleming's projects for 2 years). She is supportive and willing to help, as needed. Happy to debrief when you have a moment. Cheers, M.

 Sent:
 Sat, 3 Dec 2016 11:18:55 -0500

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Burklow, John (NIH/OD) [E]

Subject: Fwd: Key Republicans urge Trump to keep Francis Collins as NIH director

Francis, in case you had not seen this. M.

Article in Stat today.

Key Republicans urge Trump to keep Francis Collins as NIH director

WASHINGTON — In a letter sent Friday, top congressional Republicans urged Presidentelect Donald Trump to keep Dr. Francis Collins as director of the National Institutes of Health.

Collins received the endorsement from key GOP members of Congress: outgoing House and Energy Commerce chairman Fred Upton, Senate health committee chairman Lamar Alexander, and the two chairmen of the appropriations committees that oversee NIH: Senator Roy Blunt of Missouri and Congressman Tom Cole of Oklahoma.

"Dr. Collins is the right person, at the right time, to continue to lead the world's premier biomedical research agency," they said in the letter.

Trump has made few comments on NIH, aside from a 2015 remark that he had heard "terrible" things. But many in Washington have speculated since the election that Collins could end up staying on under Trump.

The agency is in the midst of launching several major research efforts, including the Precision Medicine Initiative and Vice President Joe Biden's cancer moonshot. Collins, who has served as director since 2009, has been instrumental to those programs.

The only other known contender for the job is Congressman Andy Harris of Maryland, a Republican who has openly lobbied for the job in the past few days. But a lobbyist who works on medical research policy told STAT on Friday that even other Republicans on the Hill might prefer to see Collins stay in the role.

The letter sent to Trump on Friday seems to confirm that.

"Dr. Collins has a scientific vision. You can agree or disagree with it, but that was his perspective as a leader," said the lobbyist, who spoke on the condition of anonymity to discuss the matter. "He's worked with the [Obama] administration to come up with big initiatives to capture the imagination."

 Sent:
 Thu, 6 Oct 2016 22:39:58 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Heads up

Hi, Francis. Last Friday I met with Fred Siegel, who was recommended by Paul Montrone as a possible Board Member. He is terrific, actually.

(b) (6)

Fred heads Beacon Capital, a private real estate investment trust (REIT). During our conversation he mentioned they have their annual meeting every April and noted that they never have invited a speaker from the medical field. As a big fan, he wondered if you might be able to be the keynote speaker next year.

I told him I did not know but that he should send a letter of invitation directly to you. (I asked for more information and he sent the note below. The list of speakers is very impressive.) If this is not something you would consider, just let me know. Otherwise, you should be getting the formal invitation soon.

Best, Maria

Begin forwarded message:

From: "Seigel, Fred" <FSeigel@beaconcapital.com>

**Date:** October 3, 2016 at 12:15:38 PM EDT **To:** "mfreire@fnih.org" <mfreire@fnih.org>

Subject: Dr. Collins:

# mfreire@fnih.org

Dear Maria,

It was wonderful to meet you on Friday and I am honored by your consideration of me as a potential board member. I have great admiration for the mission of the NIH and the foundation.

As a follow-up to my inquiry about Dr. Collins addressing our annual investor conference during dinner on Monday, April 24, 2017, I wanted to provide some basic information. The event will be our welcoming reception and dinner on Monday, April 24, 2017, preceding our meetings that will take place the following day. The events will take place at the Seaport Hotel in Boston.

We have a diverse group of institutional investors, including:

- Public pensions such as CalSTRS, New York State Common Retirement Fund, Oregon Public Employees Retirement Fund, State of Wisconsin Investment Board
- Corporate pensions such as GE, AT&T
- Financial service firms such as Allstate Insurance, Liberty Mutual Insurance, Erie Insurance
- Endowments such as Harvard, Cornell, Dartmouth, Northwestern, Wellesley
- Foundations such as W.K. Kellogg Foundation, Boston Foundation, Irvine Foundation, Mott Foundation, Irvine Foundation
- Non-U.S. investors such as Allianz Insurance, Ivanhoe Cambridge, Generali Insurance

We expect to have 80 to 100 people in attendance, including some of my colleagues at Beacon. Our previous speakers have included:

- Larry Summers, former Secretary of the U.S. Treasury
- Leon Panetta, former Presidential Chief of Staff, CIA Director, and U.S. Secretary of Defense
- Laura D'Andrea Tyson, former Chair of the U.S. President's Council of Economic Advisers
- Allen Sinai, Co-Founder, CEO and Chief Global Economist and Strategist at Decision Economics, Inc.
- Ken Burns, documentarian
- Doris Kearns Goodwin, historian and author
- Wes Moore, author and social entrepreneur
- Bryan Stevenson, lawyer, social justice activist, founder and executive director of the Equal Justice Initiative

I know Dr. Collins has tremendous demands on his schedule, but I think he would find this a very interesting event with an engaging audience.

Thank you again for your consideration. I look forward to speaking with you again soon.

Best regards, Fred

**Sent:** Thu, 15 Sep 2016 14:22:12 -0400

**To:** Collins, Francis (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];McGarey, Barbara (NIH/OD) [E];Burklow, John (NIH/OD) [E];Koroshetz, Walter

(NIH/NINDS) [E]

Cc: James, Stephanie (FNIH) [T]; Wolf-Rodda, Julie (FNIH) [T]; Klock, Kevin (FNIH)

[T];Meltzer, Abbey (FNIH) [T]

Subject: IG - SHRP

Attachments: Letter.pdf

Francis,

Please see below, Maria

E&C Leaders Request Thorough Independent Review by HHS Watchdog in Wake of NFL-NIH Grant

Sep 15, 2016 Press Release

In an Effort to Ensure the Integrity of the NIH Grant Process and Advance Important Research, Leaders Request HHS Inspector General Examine Public-Private Partnerships

WASHINGTON, DC – Republican leaders of the House Energy and Commerce Committee today sent a referral letter to HHS' Office of the Inspector General regarding an NIH grant awarded for research related to traumatic brain injury that became a source of public controversy. The grant was to be funded through a donation by the National Football League to the Foundation for the National Institutes for Health (FNIH) as part of the Sports and Health Research Program (SHRP) – a public-private partnership with the National Institutes of Health (NIH). The SHRP was established for the purpose of supporting "research on serious medical conditions prominent in athletes and relevant to the general population."

Earlier this year, media outlets and a subsequent report by the committee's Democratic staff alleged the NFL attempted to inappropriately influence NIH decision-making related to this grant award. However, based on the information available to Republican committee staff, these reports failed to address critical questions related to the conduct of NIH that may have contributed to the controversy and delay in awarding this grant.

In order to ensure the integrity of NIH grant processes, prevent future breakdowns in NIH grant decision-making, and advance the critical research related to head trauma and sports related injuries, the committee leaders pose five questions for potential examination by the independent HHS watchdog:

- Why didn't the NIH require the NFL to pay pursuant to the terms of the agreement?
- If the actions of the NFL or its advisors were clearly inappropriate, as the Democratic staff
  report concludes, why did NIH and FNIH engage with representatives of the League and
  perpetuate the impression that the dialogue was appropriate? If confronted with inappropriate
  conduct by a donor, what are NIH's responsibilities to flag and address such behavior?

- Did NIH adhere to the terms of the MOU regarding donor communications?
- What are NIH policies for the control of non-public information, including information related to Notice of Grant Awards, as well as non-funded grant proposals? Were they followed in this series of events?
- How does NIH evaluate conflicts of interest between applicants and donors in public-private partnership grant programs such as SHRP?
- The Energy and Commerce Committee has been conducting a broad review of concussions and brain injuries in America. The parties involved in this controversial grant making process all play an important role in addressing that challenge.

In the letter to the HHS OIG, the committee leaders concluded, "While this grant award has become an unfortunate distraction from the greater issue of improving the science of traumatic brain injury (TBI), given the significant public attention to these events, it is clear that a thorough and objective review by the HHS OIG is necessary. This review is important to the strength and integrity of the SHRP, as well as the independence of NIH decision-making."

The letter was signed by Energy and Commerce Committee Chairman Fred Upton (R-MI), Oversight and Investigations Subcommittee Chairman Tim Murphy (R-PA), Health Subcommittee Chairman Joseph Pitts (R-PA), and Commerce, Manufacturing, and Trade Subcommittee Chairman Michael C. Burgess, M.D. (R-TX).

ONE HUNDRED FOURTEENTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115

Majority (202) 225-2927 Minority (202) 225-3641

September 15, 2016

The Honorable Daniel Levinson Inspector General Office of Inspector General U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, DC 20201

Dear Mr. Levinson:

In September 2012, the National Football League (NFL or the League) provided a donation of \$30 million to the Foundation for National Institutes of Health (FNIH) for the Sports and Health Research Program (SHRP) – a public-private partnership with the National Institutes of Health (NIH). The SHRP was established for the purpose of supporting "research on serious medical conditions prominent in athletes and relevant to the general population." Consistent with other FNIH programs, SHRP has policies and procedures to ensure the integrity and objectivity of NIH research funded through the public-private partnership.

In December 2015, ESPN's Outside the Lines published the first of a series of reports alleging that the NFL attempted to influence NIH decision-making for a research grant to be funded through SHRP.<sup>2</sup> In response to the initial ESPN report, Democratic Members of this Committee launched an investigation into the NFL's actions and the effect on the independence of NIH decisions related to the grant. In May 2016, the Democratic staff released a report which

<sup>&</sup>lt;sup>1</sup> Press Release, Foundation of the National Institutes of Health, "NFL Commits \$30 Million Donation to FNIH to Support Medical Research (Sept. 5, 2012) available at http://www.fnih.org/news/press-releases/national-football-league-commits-30-million-donation

<sup>&</sup>lt;sup>2</sup> Steve Fainaru et. al., ESPN, "NFL backs away from funding BU brain study; NIH to fund instead" (December 22, 2015) available at http://espn.go.com/espn/print?id=14417386#.

concluded that the NFL had attempted to inappropriately influence NIH decision-making, but that "NIH leadership maintained the integrity of the science and the grant review process."

Based on the information available to the Republican staff, however, there appear to be important questions and concerns related to these events that have not been adequately vetted or addressed. The FNIH was established by Congress in 1990 to allow the NIH to secure the benefits of public-private partnerships.<sup>4</sup> These public-private partnerships through FNIH are carefully structured to prevent donors from improperly influencing NIH use of funds in the execution of its inherently governmental responsibilities. In this case, however, it appears that NHI's actions may have contributed to the breakdown of the structures and processes that exist to preserve the integrity of NIH research. Specifically, if the conduct of the NFL or its advisors was, in fact, inappropriate. NIH not only failed to identify and address this behavior, but rather encouraged ongoing discussion, thus creating a perception that the League had input on the use of SHRP funds. This grant award has become the source of tremendous public debate and, therefore, clear answers and lessons are necessary. For these reasons, the Committee refers this matter to your attention and requests a thorough and objective review by the Office of Inspector General to assess whether the policies and procedures concerning public-private partnerships under the authority of FNIH were followed, and if not, what revisions or reforms should be considered. This will help SHRP, and other public-private partnerships, avoid similar distractions in the future so all parties can focus on what matters most – the science.

## **Background**

The Sports and Health Research Program (SHRP) was created in September 2012 for the purpose of accelerating "research on serious medical conditions prominent in athletes and relevant to the general population." The program was established in response to interest from the NFL, and the League provided a founding donation of \$30 million. While the program is designed to address health concerns across all sports, to date, the NFL remains the only donor to the program.

The SHRP is administered through interparty agreements among the donor (NFL), FNIH, and NIH. There is a Memorandum of Understanding (MOU) between FNIH and NIH which outlines the responsibilities of NIH and FNIH for administration of the SHRP. In addition, there is a Letter of Agreement (LOA) between the FNIH and the NFL which establishes the terms of

<sup>&</sup>lt;sup>3</sup> Democratic Staff Report, Committee on Energy and Commerce, "The National Football League's Attempt to Influence Funding Decisions at the National Institutes of Health," (May 23, 2016), at 3 (Hereinafter "Democratic Staff Report").

<sup>&</sup>lt;sup>4</sup> The NIH is prohibited from soliciting private donations so Congress authorized the establishment of the Foundation in 1990 as a not-for-profit 501(c)(3) to facilitate public-private partnerships that support NIH's mission. <sup>5</sup> Press Release, Foundation of the National Institutes of Health, "NFL Commits \$30 Million Donation to FNIH to Support Medical Research (Sept. 5, 2012) available at http://www.fnih.org/news/press-releases/national-football-league-commits-30-million-donation

the NFL's donation to SHRP. There are several key aspects of these agreements relevant to this referral:

- 1) Research Plans The LOA between the NFL and FNIH outlines 11 areas of research interest for SHRP, three related to head trauma, six discrete health concerns (e.g. cardiac death in young athletes, heat and hydration illness, the effects of drugs and performance enhancing substances, etc.), and two related to third party or donor proposals. Specific research priorities within or related to these areas of interest are identified through collaborative discussions between the NFL, FNIH, and NIH. Once a research priority of mutual interest is identified, the NIH is responsible for developing a Research Plan, which FNIH then provides to the NFL. There may be additional discussions between all three parties about the specifics of the Research Plan. Once there is agreement and the Research Plan is executed by all three parties, all responsibility for execution of the Research Plan transfers to NIH. The LOA specifically states that the "DONOR acknowledges and agrees that NIH will have responsibility for and control over the scientific and administrative aspects of the Research Plans it manages under the program, including but not limited to holding workshops, developing and posting calls for applications, reviewing applications, determining grantees, awarding grants, overseeing the grants, including the scientific and financial progress of grantees, monitoring data sharing plans, and publication of research results related to the program."<sup>7</sup> This is consistent with NIH policy regarding donor influence.8
- 2) Donor Communications FNIH is responsible for all interactions with the donor, the NFL. In addition to providing required scientific progress and financial reports, and coordinating public communications, they are also responsible for responding to "reasonable requests for information regarding the program," and using "reasonable efforts to facilitate resolution of any Donor related issues that arise with respect to the applicable project."
- 3) Responsibility for Payment Under the terms of the LOA, once a Research Plan is executed by all parties, the donor, in this case the NFL, is responsible for payments set forth in the Research Plan. Section 9(b) of the LOA specifically notes that even if the NFL terminated the Agreement with FNIH which they may do "for any reason or for no reason upon providing FNIH thirty (30) days' advance written notice" that would not

<sup>&</sup>lt;sup>6</sup> Master Letter of Agreement between National Football League and Foundation for the National Institutes of Health, The Sports Health and Research Program (Sept. 1, 2012), at 1-2 (Hereinafter "LOA").

<sup>7</sup> Id., at 3.

<sup>&</sup>lt;sup>8</sup> NIH Policy Manual, *1135-Gifts Administration* (October 5, 2011) available at https://omal.od.nih.gov/manualchapters/management/1135/,

<sup>&</sup>lt;sup>9</sup> Memorandum of Understanding between The Foundation for the National Institutes of Health and Office of the Director, National Institutes of Health, The Sports Health and Research Program, at 4 (Hereinafter "MOU").

"terminate or otherwise relieve any of NFL's obligations for payment of any installments that are set forth in any executed Research Plan(s)." 10

4) Request for Payment – The LOA states that "upon agreement by DONOR, the FNIH, and NIH on the Research Plan, the FNIH will transfer DONOR funds to NIH." FNIH clarified that this is done as needed, based on a general schedule outlined in the Research Plan. FNIH added that the funding schedules in the Research Plan are indicative and therefore, they do not invoice a donor until they receive a specific request from NIH. 12

Since the inception of the SHRP, the NFL, NIH, and FNIH have executed five Research Plans. The first four Research Plans proceeded without concern or controversy. The events in question center on Research Plan 5, executed by the parties in July 2014. The Research Plan contained three primary components: 1) a longitudinal study to detect early stages and progression of chronic traumatic encephalopathy (CTE); 2) a workshop to plan a longitudinal study on youth and sport health; and (3) semiannual stakeholder meetings. The bulk of the funding under Research Plan 5, approximately \$16 million, was scheduled to go to a grant for the longitudinal study of CTE in high risk adults.

## The Democratic Staff Investigation

In response to the December 2015 ESPN report, on January 7, 2016, Democratic members of this Committee opened an investigation. In letters to NIH and FNIH, the Democratic members requested documents and information necessary to inform their understanding of "the agreements between NFL, NIH, and FNIH and the NFL's involvement in the administration of its \$30 million 'unrestricted' donation to NIH."

The Committee's Republican staff participated in three initial briefings related to the Democratic staff's investigation, two with Dr. Walter Koroshetz, Director of the National Institute of Neurological Disorders and Stroke at NIH, and one with Dr. Maria Friere, President and Executive Director of FNIH. The Republican staff received a limited number of documents produced by NIH and email communications provided by FNIH. Further, after the second briefing with Dr. Koroshetz, (on February 10, 2016), the Republican staff was not informed of further briefings or correspondence related to the Democratic staff's investigation.

11 LOA, at 4.

<sup>&</sup>lt;sup>10</sup> LOA, at 6

<sup>&</sup>lt;sup>12</sup> Summary provided by the Foundation for the National Institutes of Health, "Sports and Health Research Program – Grant Structure" (on file with Committee Staff).

<sup>&</sup>lt;sup>13</sup> Sports Health and Research Program, Research Plan, Schedule No. 5 (July 24, 2015).

<sup>&</sup>lt;sup>14</sup> Letter from Ranking Member Frank Pallone, Jr. et al., Committee on Energy and Commerce, to Dr. Francis Collins, Director, NIH (January 7, 2016); Letter from Ranking Member Frank Pallone, Jr. et al., Committee on Energy and Commerce, to Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health (January 7, 2016).

On May 23, 2016, the Democratic staff released a report summarizing the results of their investigation. The report contained six findings and five recommendations.<sup>15</sup>

## Findings:

- 1. The NFL improperly attempted to influence the grant selection process at NIH.
- 2. The NFL's Head, Neck and Spine Committee members played an inappropriate role in attempting to influence the outcome of the grant selection process.
- 3. The NFL's rationalization that the Boston University study did not match their request for a longitudinal study is unfounded.
- 4. FNIH did not adequately fulfill its role of serving as an intermediary between NIH and the NFL.
- 5. NIH leadership maintained the integrity of the science and the grant review process.
- 6. The NFL did not carry out its commitment to respect the science and prioritize health and safety.

#### Recommendations:

- 1. FNIH must establish clearer guidelines regarding donor communications with NIH.
- FNIH must come to a mutual understanding with donors at the beginning of the process regarding their degree of influence over the research they are funding and remind donors that NIH policy prohibits them from exerting influence at any point in the grant decision-making process.
- 3. FNIH should provide donors with the clear, unambiguous language from the NIH Policy Manual, which states that a donor may not dictate terms that include "any delegation of NIH's inherently governmental responsibilities or decision-making," or "participation in peer review or otherwise exert real or potential influence in grant or contract decision-making."
- 4. NIH and FNIH should jointly develop a process to address concerns about donors acting improperly.
- 5. The NFL, FNIH, and NIH should amend their current agreements to ensure that each party has a clear understanding of its role for the remainder of this partnership.

<sup>&</sup>lt;sup>15</sup> Democratic Staff Report, at 3-4.

## Stakeholder Reaction to the Democratic Staff Report

In response to the Democratic staff report, several members of the NFL's Head, Neck and Spine Committee (HNS) publically voiced concerns about the conclusions regarding their conduct. In addition, these independent medical advisors asserted that they were never contacted by the Democratic committee staff prior to the release of the report. The FNIH also voiced disagreement with the report. In a public response, FNIH stated:

May 23, 2016 — This morning, the Democratic Staff of the Committee on Energy and Commerce issued a report on the Sports and Health Research Program (SHRP), a partnership among the National Institutes of Health (NIH), National Football League (NFL) and the Foundation for the National Institutes of Health (FNIH). The following is the FNIH's response to the report.

The FNIH acted appropriately, with integrity and transparency, in fulfilling its mandate under SHRP. As acknowledged by the Democratic Staff report, the governing documents among the FNIH, NIH and NFL made clear that the NIH had exclusive control over the scientific and administrative aspects of the program.

The report makes recommendations regarding communication issues that the FNIH has already identified and taken steps to address. The FNIH has strengthened protocols around communications among NIH, NIH researchers and FNIH donors that will prevent unauthorized contact among parties.

The FNIH has had a long history of successful and productive publicprivate partnerships in support of the NIH mission. These adjustments to governing agreements will help ensure the success of future scientific partnerships in support of human health.<sup>18</sup>

Based on the limited information available to the Republican staff, as well as the subsequent concerns raised by the Members of the HNS and FNIH, the Republican staff identified several issues regarding the roles and responsibilities of NIH that warrant the attention of the OIG. Resolving these questions will ensure the integrity of NIH grant processes and

<sup>&</sup>lt;sup>16</sup> Dr. Hunt Batjer et. at. The Hill, "Committee's NFL concussion report gives wrong impression." (June 15, 2016) available at http://64.147.104.30/opinion/letters/283654-committees-nfl-concussion-report-gives-wrong-impression.

<sup>&</sup>lt;sup>18</sup>Statement, Foundation for the National Institutes of Health, "The FNIH's Statement on the Democratic Staff Report of the Committee on Energy and Commerce," (May 23, 2016) available at <a href="http://www.fnih.org/news/announcements/the-fnihs-statement-on-the-democratic-staff-report-of-the-committee-on-energy-and-commerce">http://www.fnih.org/news/announcements/the-fnihs-statement-on-the-democratic-staff-report-of-the-committee-on-energy-and-commerce</a>. (Emphasis added)

decisions, strengthen SHRP, and enable all parties to eliminate the distraction and focus on what matters most – advancing critical research related to head trauma and sports related injuries.

#### Sequence of Events

As described above, the current controversy centers on the fifth Research Plan executed under SHRP. The primary component of Research Plan 5 was a \$16 million grant for a longitudinal study of CTE in high risk adults. While the NFL has expressed interest in a true longitudinal study on brain trauma, the research grant agreed to by the parties – including the NFL - under Research Plan 5 had a more limited scope and duration. The document stated:

Although a large, natural history longitudinal study of young athletes over many years would be a powerful approach to identify the population incidence and prevalence of neurological deficits caused by brain trauma, it would require several decades to complete the study. Given the urgency of the problem, an alternative approach is to focus on high risk individuals with symptoms and medical history suggestive of CTE. In such individuals it may be possible to detect progression over the 3-5 year time span of this study. Therefore, this initiative aims to support a 7-year longitudinal, hypothesis-driven study to detect, define and monitor the progression of CTE in high-risk middle-aged adults, along with appropriate control studies.<sup>19</sup>

Research Plan 5 was executed by all three parties in July 2014. Upon execution, NIH assumed responsibility for issuing the Request for Applications (RFA), reviewing submissions, and making a funding decision. The National Institute of Neurological Disorders and Stroke (NINDS) Council met in May 2015 and recommended awarding the grant to a multi-center group led by Dr. Robert Stern from Boston University (BU).

Dr. Stern and a number of his colleagues at BU are among the most recognized experts and researchers on neurodegenerative diseases and Traumatic Brain Injury (TBI). Based on their research, they have been vocal about the link between football and long-term cognitive impairment, including CTE. This has, at times, created tension with the NFL. There is not, however, a complete lack of engagement between the League and BU. For example, Dr. Robert Cantu, a respected brain trauma expert from the Boston University School of Medicine is a medical advisor for the League. In addition, Dr. Ann Mckee – a nationally recognized neuropathologist from BU —received a grant award from an earlier SHRP Research Plan — without controversy or opposition.

<sup>&</sup>lt;sup>19</sup> Id., at 1-2. The NFL has raised concerns that the grant award for Research Plan 5 was inconsistent with their understanding of the research to be conducted. However, as noted in the Democratic Staff report (pp.28-30), the grant does appear consistent with the research agreed to by all parties in Research Plan 5.

Following the Council meeting in May 2015, the BU group was informed that they would receive the grant award. Normally, this information is closely held until NIH publicizes the Notice of Grant Award (NGA). However, prior to the NGA, one of the NFL's medical advisors, Dr. Elliot Pellman, contacted the President and Executive Director of FNIH, Dr. Maria Freire about the award. In a June 17, 2015 email, Dr. Pellman shared concerns that he and other NFL medical advisors had about the rumored award decision. According to Dr. Freire, award decisions are supposed to be confidential and she could not recall a previous example of a donor learning this information before it was made public. In fact, prior to Dr. Pellman's email, Dr. Freire indicated that FNIH was unaware of NIH's award decision. 22

Dr. Pellman's email raises questions about how the NFL or its advisors learned of NINDS' grant award recommendation. The Democratic staff report suggests the awardee, Dr. Stern, informed the NFL directly.<sup>23</sup> It is unclear, however, whether Dr. Stern's outreach occurred before or after Dr. Pellman's email to FNIH.<sup>24</sup> Regardless, the fact that a donor was made aware of an award decision before it was made public raises questions regarding NIH rules or guidance regarding confidentiality prior to the public NGA.

After receiving Dr. Pellman's note, Dr. Freire forwarded the message to Dr. Koroshetz, Director of NINDS. He responded to her email the next evening, stating:

Yes we know this was coming. Lot of history here. But our process was not tainted and all above board. The grant will go to a multisite group around the country. NINDS will manage it. The data will be believable and unbiased. Trouble is of course is [sic] that the group is led by the people who first broke the science open and NFL owners and leadership think of them as the creators of the problem. I think we need to go to Betsy Nabel first and get her on board (Betsy is their chief medical officer). We spoke this week.<sup>25</sup>

It is worth noting that the email from Dr. Pellman made no reference to concerns about the NIH process, only the group selected to receive the award and its ability to be "unbiased and collaborative." In fact, the day before, June 17, 2015 – the same day Dr. Pellman contacted FNIH – Dr. Koroshetz emailed Dr. Nabel, the NFL's chief medical adviser, in response to a number of issues related to brain injury research he had discussed with her earlier that day. The

<sup>&</sup>lt;sup>20</sup> Email from Dr. Elliot Pellman to Dr. Maria Freire, FNJH (June 17, 2015) (On file with Committee Staff).

<sup>&</sup>lt;sup>21</sup> Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health to staff of the Committee on Energy and Commerce (January 28, 2016).
<sup>22</sup> Id.

<sup>&</sup>lt;sup>23</sup> Democratic Staff Report, at 15.

<sup>&</sup>lt;sup>24</sup> Email from Jeff Miller, Exec. VP for Player Health and Safety, NFL to Republican Staff, Committee on Energy and Commerce (June 1, 2016) (On file with Committee Staff).

<sup>&</sup>lt;sup>25</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Maria Freire, FNIH (June 18, 2015) (On File with Committee Staff).

<sup>&</sup>lt;sup>26</sup> Email from Dr. Elliot Pellman to Dr. Maria Freire, FNIH (June 17, 2015) (On file with Committee Staff).

first bullet in his email notes, "[y]es the longitudinal trial that will launch soon is very multi center. Will get you details as soon as NGA is out." He also noted that an individual at Brigham and Women's Hospital – where Dr. Nabel serves as President – "is tied in to most of our activities." While Dr. Koroshetz denied discussing the grant with Dr. Nabel at that time, his email suggests they had addressed the study to some degree. 29

Shortly after responding to Dr. Freire's email on June 18, 2015, Dr. Koroshetz emailed Dr. Nabel to inform her about the outreach from Dr. Pellman to FNIH. He stated:

Got message from fNIH that NFL questioning NIH funding decision of the longitudinal study and asking fNIH to slow down the process.

So legally I don't think NIH can talk about a study [until] NGA is out. And as you know we can't allow outside parties to influence NIH funding decisions, which we made clear to NFL going in.

I am certain that the study will be high level science and unbiased. It is a cooperative agreement so NINDS sets milestones and are involved in oversight.

I understand very well the emotion around this and the complicated history. We would be happy to sit down with you, go through the study in detail and get your input once public.

Sorry to get you in the middle of this but you're the perfect position to ensure that the science advances.

Will be happy to allay concerns with NFL folks when we can publicly discuss.<sup>30</sup>

The Democratic staff report states that Dr. Nabel "emailed Dr. Koroshetz the day after Dr. Pellman emailed Dr. Koroshetz to express her own concerns." The Republican staff is unaware of any email from Dr. Pellman to Dr. Koroshetz. Further, the email cited in the Democratic staff report is dated June 23, 2015, six days after Dr. Pellman contacted FNIH. It is important to clarify that Dr. Nabel's email was in response to the email Dr. Koroshetz sent to her on June 18, 2015. In her initial response she passed along a pdf she received from the NFL,

<sup>&</sup>lt;sup>27</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Betsy Nabel (June 17, 2015) (On file with Committee Staff).

<sup>&</sup>lt;sup>28</sup> Id. [This individual was one of the recipients of the grant in question].

<sup>&</sup>lt;sup>29</sup> Briefing by Dr. Walter Koroshetz, Director of NINDS, NIH to Energy and Commerce Committee Staff (Feb 10, 2016) (On file with Committee Staff).

Email from Dr. Walter Koroshetz, NIH to Dr. Betsy Nabel (June 17, 2015) (On file with Committee Staff). [Despite his note that they could not discuss the grant until NGA was public, as noted in foomote 12, he had already hinted at one of the recipients in correspondence with Dr. Nabel].

<sup>31</sup> Democratic Staff Report, at 15.

<sup>&</sup>lt;sup>32</sup> Id.

who may have received it from a grant applicant, and shared concerns that were raised to her by the League or its advisors. She stated:

I am taking a neutral stance here, but I believe the concern is that members of the study section had published within the past two years with Dr. McKee or Dr. Cantu, who the grant applicant believes will receive the [Notice of Grant Award]. Obviously, my goal is to make sure the science goes forward.<sup>33</sup>

Dr. Koroshetz responded that he would follow up with his review staff when he returned from overseas travel.<sup>34</sup> Shortly thereafter, Dr. Nabel responded with her appreciation and an additional concern that "[a]pparently a Dr. Stern, who may also be with this group, has filed independent testimony in the NFL/Players Association settlement. I hope this group is able to approach their research in an unbiased manner."

Two days later, on June 25, 2015, Dr. Koroshetz responded to Dr. Nabel's note to inform her "NINDS can certainly try to enforce strict objectivity in the study and work the group dynamic as there are four Principal investigators." He shared the names and institutions of the three other principal investigators involved in the study, as well as a clinical site, and suggested a meeting with the principal investigators to inform the NFL medical team about the study and discuss concerns. The NGA was still not public at this time. Therefore, this offer appears to contradict his message on June 18, 2015, where he explained that NIH could not discuss the grant until the NGA was public. It is unclear what changed between June 18, 2015 and June 25, 2015 that enabled NIH to discuss a non-public grant decision, as well as why NIH did not proceed with announcing the NGA, as planned.

During the same time period, on June 22, 2015, Jeff Miller, Executive Vice President of Health and Safety for the NFL, emailed Dr. Freire to request a time to discuss the grant. At that time, Dr. Freire was under the impression that Dr. Koroshetz was reaching out to Dr. Nabel but had not heard anything about the outcome of those discussions. Mr. Miller responded, "If you want to wait for them to connect, I understand but we would like to discuss the grant with

<sup>&</sup>lt;sup>33</sup> Email from Dr. Betsy Nabel to Dr. Walter Koroshetz (June 23, 2015) (On file with Committee Staff). [As noted in the Democratic staff report, neither Dr. McKee nor Dr. Cantu are listed as primary investigators on the Notice of Award announcement. However, they are affiliated with primary institution – Boston University – and the Republican staff has not reviewed the complete grant to know if they are listed as advisors or will otherwise contribute to the work affiliated with the grant. Dr. McKee has previously received funding for CTE research through SHRP and Dr. Cantu is a medical advisor to the NFL]

Email from Dr. Walter Koroshetz, NIH to Dr. Betsy Nabel (June 22, 2015) (On file with Committee Staff).
 Email from Dr. Betsy Nabel to Dr. Walter Koroshetz, NIH (June 23, 2015) (On file with Committee Staff).

Email from Dr. Walter Koroshetz, NIH to Dr. Betsy Nabel (June 25, 2015) (On file with Committee Staff).

<sup>&</sup>lt;sup>38</sup> Email from Jeff Miller, NFL to Dr. Maria Freire, FNIH (June 22, 2015) (On file with Committee Staff).
<sup>39</sup> Based on email records available to the Committee, FNIH was unaware of the back-and-forth between Dr. Koroshetz and Dr. Nabel until he forwarded the exchange to Dr. Freire on the evening of June 25, 2015. This appears to contradict the terms of the MOU which placed responsibility for donor communications with FNIH.

the FNIH as well." This led to a phone call between Mr. Miller and representatives of FNIH on June 26, 2015. 41

In advance of that conversation, in a series of emails between the evening of June 25, 2015, and early afternoon June 26, 2015, Dr. Koroshetz updated Dr. Freire on his conversations with Dr. Nabel and provided his suggestions for next steps. He initially recommended the offer he gave to Dr. Nabel – to set up a phone call with the principal investigators of the grant. Dr. Freire responded that FNIH felt it was best to see what the NFL wanted and offer a follow-up with him. In response, Dr. Koroshetz agreed and asked FNIH to emphasize that the grant award involved multiple groups and would have NIH oversight. He also mentioned the concerns about the review process raised by Dr. Nabel and that his program directors had examined those concerns. They found that some panel members "were recused from discussing this grant due to conflicts" but overall the "[p]rogram did think there was a high level of integrity in the review process. He added, "of course NIH is going to fund it with or without NFL support. So in fact it is high risk for the NFL to drop out." He also raised the idea of offering a potential compromise – expanding the study to include additional locations and investigators or fund related work. The reire decided to proceed with the strategy of hearing what NFL had to say on the call and then determining appropriate next steps, likely a call with Dr. Koroshetz.

On the June 26, 2015 phone call, FNIH offered to arrange a phone call with Dr. Koroshetz. As described in the Democratic staff report, this call occurred on June 29, 2015, and involved NIH, FNIH, and the representatives from the NFL and the League's HNS committee. Based on Dr. Freire's recollection – and email exchanges discussed above – the NFL and its advisers raised three main concerns with the grant award:

- 1) The NIH peer review process The League's independent medical advisors, many who have extensive experience with NIH, were concerned that members of the review panel had fies or had coauthored research with individuals fied to the grant award.
- 2) Dr. Stern's declaration In 2014, Dr. Stern filed a declaration in opposition to the NFL's proposed settlement of a class action lawsuit between the League and its players. He argued that the settlement would exclude a large number of players deserving of compensation. The League wanted to know if the declaration was included in the review process to evaluate whether it was indicative of bias.

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<sup>&</sup>lt;sup>40</sup> Email from Jeff Miller, NFL to Dr. Maria Freire, FNIH (June 23, 2015) (On file with Committee Staff).

<sup>&</sup>lt;sup>41</sup> Email from Dr. Maria Freire, FNIH to Jeff Miller, NFL (June 23, 2015) (On file with Committee Staff).

<sup>&</sup>lt;sup>42</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Maria Freire, FNIH (June 25, 2015) (On file with Committee Staff).
<sup>43</sup> Email from Dr. Maria Freire, FNIH, to Dr. Walter Koroshetz, NIH (June 26, 2015) (On file with Committee

<sup>&</sup>lt;sup>44</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Maria Freire, FNIH (June 26, 2016) (On file with Committee Staff).

<sup>45</sup> Id.

<sup>46</sup> Id

<sup>&</sup>lt;sup>47</sup> Email from Dr. Maria Freire, FNIH to Dr. Walter Koroshetz, NIH (June 26, 2015) (On file with Committee Staff). <sup>48</sup> Democratic Report, at 16.

3) Majority of SHRP funds going to a single institution – According to Dr. Freire, the NFL was concerned about a large percentage of SHRP funds going to one institution. 49 Dr. Ann McKee, another BU researcher, previously received a grant through an earlier SHRP Research Plan. Dr. Freire told Committee staff that part of the goal of the SHRP was to seed multiple research programs.<sup>50</sup>

It is unclear to what extent these concerns were addressed during the June 29, 2015 phone call. On the call, however, Dr. Koroshetz raised the potential compromise of funding multiple groups and he suggested revisiting the grant that received the second highest score during the NIH review.<sup>51</sup> As noted in the Democratic staff report, this was a University of North Carolina (UNC)-led project which included two members of the NFL HNS Committee as principal investigators.52

While the NFL and its advisors certainly raised concerns about the NIH review process and award decision, it does not appear that anyone affiliated with the League had requested or expressed interest in an alternative path forward prior to this proposal being suggested by NIH. Further, there is nothing in the record available to Republican staff to suggest that the NFL advocated for consideration of this specific study prior to this suggestion by NIH or in subsequent discussions related to this grant.

Subsequent media reports disclosed that Dr. Richard Ellenbogen, Professor and Chairman of the Department of Neurological Surgery at the University of Washington School of Medicine, and Co-Chair of the NFL's HNS Committee, was listed as a ""minor consultant" on the UNC grant application.<sup>53</sup> According to Dr. Ellenbogen, he had never seen the grant application and did not know he was named as an advisor.<sup>54</sup> He was, however, among the members of the HNS Committee that had concerns about the award decision process and he was a participant for at least a portion of the June 29, 2015 conference call with Dr. Koroshetz. 55

Several days after the June 29, 2015 phone call, Dr. Ellenbogen sent an email to Dr. Koroshetz. He stated:

<sup>52</sup> Id. Based on the information available to Republican staff, these individuals were notinvolved in the dialogue with

<sup>54</sup> Briefing by Dr. Richard Ellenbogen et al. to the Republican staff of the Committee on Energy and Commerce

<sup>48</sup> Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health to staff of the Committee on Energy and Commerce (January 28, 2016).

<sup>51</sup> Democratic Report., at 17.

<sup>&</sup>lt;sup>53</sup> Steve Painaru et al., ESPN, NFL donations to brain research benefit league-linked doctors, raise worries about influence on science (Feb. 4, 2016) available at http://espn.go.com/espn/otl/story/ /id/14711203/nfl-donationsbrain-research-benefit-league-linked-doctors-raise-worries-influence-science-lines.

<sup>(</sup>May 31, 2015).

55 Id. Dr. Ellenbogen informed the Republican staff that he was only on the call for a few minutes before he had to drop off.

This is just a note to thank you for your time and listening to the concerns of your academic team who has long believed in the gravitas and importance of supporting NIH. I am not writing [as] the leader of the HNS committee albeit, that is a job I do without financial compensation and from that platform we have gotten 50 states to pass the Zack Lystedt Law and money put aside for important research. I am writing you as a person who has been very grateful for all the NINDS support my department in particular and the UW has received over the years. I am a solution oriented person. I very much like your suggestion that the route out of this issue will be awarding the grant to two discrete groups and splitting the money equally with an oversight committee. At the end of the day, it would be the right decision even if there were no concerns raised about the reviewer's bias or the Stern statement. It is both 100% in keeping with the successful 1st phase of the NIH/fNIH grants and it is in the spirit of "we need to follow the science by many research teams in an unbiased manner." Your solutions bring "equipoise" to the question and to the potential controversy down the line, and is simply the right thing to do. [T]hanks for suggesting it... As a surgeon/scientist laboring in the TBI world for years, I see the gift in it...<sup>56</sup>

The Democratic staff report does not acknowledge or address this correspondence. It does, however, describe Dr. Koroshetz's recollection of a subsequent phone call with Dr. Ellenbogen. According to Dr. Koroshetz, Dr. Ellenbogen reiterated his opposition to awarding the grant to the group from Boston University and suggested that he could not recommend the NFL fund the study. 57

In a conversation with the Republican staff, Dr. Ellenbogen acknowledged a phone call with Dr. Koroshetz but strongly disagreed with the account of this conversation in the Democratic staff report. He does not recall expressing any opposition to funding the BU study. Based on his recollection, he did not want to prevent Boston University from receiving funds, but supported Dr. Koroshetz's suggestion of incorporating multiple research teams. He added that it would only harm a fellow NFL medical advisor if Boston University did not receive the grant because he understood or assumed that Dr. Robert Cantu would be involved in the research led by Dr. Stern.

Email from Dr. Richard Ellenbogen to Dr. Walter Koroshetz (July 1, 2015) (On File with Committee Staff).
 Democratic Staff report, at 18.

<sup>&</sup>lt;sup>58</sup> Briefing by Dr. Richard Ellenbogen et al. with the Republican staff of the Committee on Energy and Commerce (May 31, 2016).
<sup>59</sup> Id.

<sup>&</sup>lt;sup>60</sup> Id. [It is unclear if Dr. Cantu was, in fact, involved in Dr. Stern's research. He is not listed as a Principal Investigator but he is affiliated with Boston University and his research has focused on similar concerns.

According to Dr. Ellenbogen, the phone call with Dr. Koroshetz occurred after Dr. Koroshetz reached out to him to discuss the proposal for funding two studies.<sup>61</sup> He recalls being informed that in order to fund two studies. NIH would need an additional \$15 million from the NFL. 62 Otherwise, NINDS may have to reallocate money, placing other NINDS research in jeopardy. At the time. Dr. Ellenbogen had a grant proposal, completely separate and unrelated to SHRP, under review at NINDS and he came away from the conversation with the impression that if the NFL could not provide the additional funds, NINDS would have to reallocate resources and his unaffiliated proposal would be at risk. 63 Jeff Miller informed the Republican staff that he assumed the two studies would split the existing \$16 million in SHRP funding until Dr. Ellenbogen informed him of the conversation with Dr. Koroshetz.<sup>64</sup>

The Republican staff has not reconciled the differing accounts of this phone call. However, both versions raise questions and concerns. If Dr. Koroshetz's account is accurate, it raises questions not only about the propriety of Dr. Ellenbogen's involvement, as suggested in the Democratic staff report, but also about Dr. Koroshetz and why he continued to engage Dr. Ellenbogen, as discussed below. If Dr. Ellenbogen's account is accurate, it raises concern about the propriety of an NIH employee discussing a funding request with an individual affiliated with a donor.

Based on the documents and information available to the Republican staff, there was no further contact among the parties until July 7, 2015, when Dr. Nabel reached out to Dr. Freire to introduce herself and request a phone call to discuss next steps. 65 It is unclear whether the two communicated before Dr. Freire had to leave the country; however, on July 10, 2015, Dr. Koroshetz contacted Dr. Nabel. He explained that he spoke to Dr. Freire and requested a time to talk with Dr. Nabel. He also provided additional information on the NIH's conflict of interest (COI) rules and the bottom line assessment that there were no conflicts between the peer review panel and the grant awardees for the SHRP grant. 66 On July 10, 2015, Dr. Nabel emailed Dr. Freire and stated, "Let's connect when you return. No rush. Walter and I had a good conversation. I am hopeful we will find a path through this."<sup>67</sup> The Republican staff is unaware of the substance of the discussion that took place between Dr. Koroshetz and Dr. Nabel.

In early August 2015, there were further discussions between FNIH and representatives from the NFL. At the time, there was a general understanding that Dr. Koroshetz would propose the idea of two studies; however, it was unclear how they would be funded. After a discussion

<sup>&</sup>lt;sup>61</sup> Id. [The Committee staff has not confirmed the exact date of this conversation].

<sup>62</sup> Id.

<sup>63</sup> *Id.* 64 *Id.* 

<sup>&</sup>lt;sup>65</sup> Email from Dr. Betsy Nabel to Dr. Maria Freire, FNIH (July 7, 2015) (On File with Committee Staff).

<sup>66</sup> Email from Dr. Walter Koroshetz to Dr. Betsy Nabel (July 10,2015) (On File with Committee Staff). [This conflicts with a previous email to Dr. Freire where he noted that some reviewers were barred from discussing due to conflict – see e.g. footnote 23]

67 Email from Dr. Betsy Nabel to Dr. Maria Freire, FNIH (July 10, 2015) (On File with Committee Staff).

between FNIH and Dr. Nabel, on August 12, 2015, Dr. Freire emailed Dr. Nabel to provide an update on the situation. She stated:

I spoke to Walter; he is ready to go to Council (September 9<sup>th</sup>!) with the proposal we discussed. He will make the case that having more sites and broader range of investigators will make for a much stronger study. That said, he doubts Council will agree to fund the second grant if the monies have to come entirely from NINDS, if he can find the funds. I am pretty sure we could move the needle substantially if we could get the \$10M we discussed from NFL – Walter would have to find \$4M.<sup>68</sup>

Dr. Nabel responded, adding Jeff Miller to the discussion. She noted "I'm not sure the NFL will have incremental funds. Jeff will contract [sic] you both directly to discuss further... In the interest of supporting the best science and the health of current and former players, I hope we can find a resolution." After another discussion with FNIH, on August 17, 2015, Jeff Miller emailed Dr. Koroshetz, cc'ing FNIH. He stated "After a conversation with Dr. Freire and some understanding of the request for further NFL investment, I am hoping we can schedule a time to meet with in the next few days." While the parties attempted to find a time for this discussion, on August 19, 2015, Dr. Freire emailed Jeff Miller to relay the outcome of a conversation with Dr. Koroshetz. She stated:

I had a very good conversation with Walter. It is my understanding that he will present his proposal to fund the top 2 projects to the NINDS Council on September 9/10. He understands that there may not be any additional fund for this from you. Nevertheless, he is willing to go to Council with the proposal because he realizes that this strategy is scientifically very solid. Having said this, Walter is realistic and knows that it will be a long-shot to get the funds from his budget. He is open to finding alternative funding structures that might make the funding of the 2 proposals possible...<sup>71</sup>

There is evidence to suggest there was an additional phone call between all parties at the end of August 2015, likely in response to Jeff Miller's request on August 17, 2015. Email records indicate there was a call scheduled on August 27, 2015, for "the follow-up discussion about the request for further NFL investment." The call was to include NIH, FNIH, and the NFL, as well as several medical advisors from the League's HNS Committee.

<sup>&</sup>lt;sup>68</sup> Email from Dr. Maria Freire, FNIH to Dr. Betsy Nabel (August 12, 2015) (On File with Committee Staff).

<sup>&</sup>lt;sup>69</sup> Email from Dr. Betsy Nabel to Dr. Maria Freire, FNIH (August 12, 2015) (On File with Committee Staff).
<sup>70</sup> Email from Jeff Miller, NFL to Dr. Walter Koroshetz, NIH (August 17, 2015) (On File with Committee Staff).

<sup>&</sup>lt;sup>71</sup> Email from Dr. Maria Freire, FNIH to Jeff Miller, NFL (August 19, 2015) (On File with Committee Staff).

<sup>&</sup>lt;sup>72</sup> Meeting Invite from Dr. Walter Koroshetz

Dr. Ellenbogen was unavailable to participate in the August 27<sup>th</sup> call, which prompted Dr. Koroshetz to contact Jeff Miller and ask "thoughts on how best to include Rich?" Dr. Koroshetz also reached out to Dr. Ellenbogen directly to explain the purpose of the call. He stated: "Jeff called the meeting. I will take his lead. Definitely time is key as council is Sept 10. I am working off the last plan which seemed agreeable to all – to propose funding two studies. How council will vote is hard to say given price tag. But that's the plan." Shortly thereafter Dr. Ellenbogen responded:

Thank-you Walter! I think the science will have bigger impact with two groups and especially if one has no history. This is an important question for people like myself who have a lab but also see the TBI patients whose parents are very conflicted about sports.<sup>75</sup>

The correspondence in advance of the August 27, 2015 call further illuminates the concerns raised by these events. The fact that Dr. Koroshetz reached out to the NFL to try to find a way to include Dr. Ellenbogen – who, based on Dr. Koroshetz's account, was highlighted in the Democratic staff report for his inappropriate involvement and communication with NIH – suggests NIH either did not consider these communications to be inappropriate or failed to adhere to its own rules regarding donor influence<sup>76</sup>.

The NINDS Council met on September 9-10, 2015, and Dr. Koroshetz presented the concept of funding two studies. The Council rejected the idea and maintained support for the original Boston University proposal. Given the importance of the study, the Council also recommended that NINDS should fund the research, if necessary.<sup>77</sup>

The Democratic staff report concluded that after the Council decision, "the NFL should have committed to funding the CTE study in full." The report also concluded that "FNIH should have been clearer with the NFL about their obligation to fund the study." However, the feedback to the NFL from both FNIH and NIH shortly after the September Council meeting suggests a different set of expectations.

Shortly after the Council decision, on September 12, 2015, Dr. Freire emailed Jeff Miller regarding a conversation she had with Dr. Koroshetz. She reported: "Spoke with Walter. All good. He will look at other needs/options and propose times for a meeting. And a glad yes on potentially having joint/overarching governance if more than one group get [sic] funded for the

Final from Dr. Walter Koroshetz, NIH to Jeff Miller, NFL (August 25, 2015) (On File with Committee Staff).

<sup>&</sup>lt;sup>74</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Richard Ellenbogen (August 25, 2015) (On File with Committee Staff).

<sup>&</sup>lt;sup>75</sup> Email from Dr. Richard Ellenbogen to Dr. Walter Koroshetz, NIH (August 25, 2015) (On File with Committee Staff).

<sup>&</sup>lt;sup>76</sup> Democratic Staff Report, at 27.

<sup>&</sup>lt;sup>77</sup> Democratic Staff Report, at 19.

<sup>&</sup>lt;sup>78</sup> Id. at 26.

<sup>&</sup>lt;sup>79</sup> Id. at 30.

longitudinal study."<sup>80</sup> Jeff Miller responded, "how quickly can we move this along?"<sup>81</sup> Shortly thereafter, Dr. Freire emailed Jeff Miller and Dr. Koroshetz. She wrote:

Thank you both for your flexibility and willingness to work to achieve a path forward that will benefit patients and science. To this end, it would be beneficial to find a time in the next week or so to meet to discuss options for projects that achieve this goal. An in-person meeting would be best, although it might difficult to achieve; a phone conversation is the next best option (but a second-best from my perspective). Jeff, I understand that you would like to ask [Dr. Nabel] and perhaps one or two members of your Head, Neck and Spine Committee to join the discussion. Walter, I know you are looking at possible grants or topics that would nicely fit the purpose. 82

Due to scheduling issues, this phone call did not occur until October 2, 2015. Based on these emails, however, it appears that the immediate response by NIH and FNIH after the Council meeting was to begin identifying additional research projects to be funded by the NFL. As documented in the Democratic staff report, when FNIH approached the NFL in mid-October about funding at least a portion of the BU grant, it appears the expectations had changed. Further, even at that point, the request was presented as if the NFL had a choice in the use of SHRP funds.

If it was clear from the Council's recommendation that NIH preferred for this study to be funded by SHRP, it is unclear why the initial feedback to the NFL focused on identifying additional funding opportunities. Directly or indirectly, this created a perception that NIH would fund the Boston University study and SHRP funds would go towards additional research.

If and when expectations changed, both NIH and FNIH failed to provide clear guidance on what was expected from the NFL. If NIH was concerned about having to use NINDS funds, they did not need to seek or wait for the NFL approval. Under the terms of the LOA, they could have requested FNIH invoice the NFL for the first year of that grant.

This narrative is not intended as a complete or definitive account of these events. Nor is it intended to assign blame or culpability. This grant award has created substantial public debate and controversy. Unfortunately, to date, there has not been a thorough and objective examination of these events. Therefore, this narrative highlights the areas of concern Republican staff believe must be incorporated in such a review to ensure that appropriate lessons are learned and applied to avoid similar outcomes in the future.

<sup>&</sup>lt;sup>80</sup> Email from Dr. Maria Freire, FNIH to Jeff Miller, NFL (September 12, 2015) (On File with Committee Staff).

Email from Jeff Miller, NFL to Dr. Maria Freire, FNIH (September 15, 2015) (On File with Committee Staff). 
82 Email from Dr. Maria Freire, FNIH to Dr. Walter Koroshetz, NIH and Jeff Miller, NFL (September 15, 2015) (On File with Committee Staff).

<sup>83</sup> Democratic Staff Report, at 20-22.

## Areas for Review

This grant has already received tremendous public scrutiny. Much of that attention, to date, has focused on the actions of the NFL and its independent advisors – and to a certain extent, FNIH. However, as documented in this letter, there are additional questions and concerns about NIH's role in these events. These include, but are not limited to:

1) Why didn't the NIH require the NFL to pay pursuant to the terms of the agreement?

Under the terms of the LOA, the NFL was responsible for payments included in any executed Research Plan. Research Plan 5 was signed by all parties in July 2014. Therefore, when the NFL raised concerns about the grant decision in June 2015, NIH had no formal obligation to delay the award. While the NFL certainly could have resisted providing the annual installments required under Research Plan 5, the LOA contained an arbitration provision for "any controversy, claim or dispute arising out of or relating to this Agreement or concerning the respective rights or obligations of the parties hereto, including breach thereof..." While this course of action may have undermined the relationship between the parties and thus compromised any potential future donations to SHRP, if FNIH and NIH were uncomfortable with the NFL's actions or concerned about the use of limited federal resources, it was an option for consideration at any point in the six months of discussion over this grant. Further, there is no evidence to suggest that the NFL would not have funded the study if so requested by NIH and FNIH. The months of collaborative discussion, however, created a situation where the use of SHRP funds apparently became more of a choice than a requirement.

2) If the actions of the NFL or its advisors were clearly inappropriate, as the Democratic staff report concludes, why did NIH and FNIH engage with representatives of the League and perpetuate the impression that the dialogue was appropriate? If confronted with inappropriate conduct by a donor, what are NIH's responsibilities to flag and address such behavior?

The Democratic staff report concludes that "[t]he NFL improperly attempted to influence the grant selection process at NIH." In the explanation of that finding, the report suggests that Dr. Koroshetz disagreed with the NFL's perception that their actions were proper and their concerns were raised in an appropriate manner. The report adds:

"[Dr. Koroshetz] expressed that the stipulations in funding agreements have consistently expressed that the NIH scientific process is out of bounds for donors. Dr. Koroshetz was aware of no other instance where a

<sup>84</sup> LOA, at 7.

<sup>85</sup> Democratic Staff Report, at 25.

<sup>86</sup> Id., at 26.

> donor raised objections to a grantee prior to the issuance of a notice of grant award (NGA)."87

Under the terms of the SHRP and NIH policy, a donor – in this case the NFL – should not be able to influence grant funding decisions after a research plan is executed. Therefore, if Dr. Koroshetz, or anyone at NIH or FNIH, felt that the NFL's actions were inappropriate, they could have asserted their authority under the terms of the SHRP and proceeded with the NGA. There is nothing in the sequence of events - as they are currently understood - that suggests anyone from NIH or FNIH pushed back or attempted to correct the NFL. Instead, the NIH and FNIH engaged in a months-long collaborative dialogue with the League, thus reinforcing the perception that there was nothing improper about these interactions.

3) Did NIH adhere to the terms of the MOU regarding donor communications?

Under the terms of the MOU between NIH and FNIH for the SHRP, FNIH is responsible for all donor communications. This includes responding to "reasonable requests for information" regarding the program," and using "reasonable efforts to facilitate resolution of any Donor related issues that arise with respect to the applicable project."88 The majority of the NFL's outreach, including the initial email from Dr. Pellman, was directed through FNIH. There were a number of examples, however, of NIH - specifically the Director of NINDS, Dr. Koroshetz communicating directly with the League's medical advisers. The evidence suggests that in many, if not most cases, NIH initiated these exchanges. While it appears that FNIH and NIH have taken steps to clarify roles and responsibilities for donor communications, it is important to ensure these measures will protect the integrity of the grant process going forward.

4) What are NIH policies for the control of non-public information, including information related to Notice of Grant Awards, as well as non-funded grant proposals? Were they followed in this series of events?

This entire episode has been complicated by apparent breakdowns in the control of nonpublic or confidential information. For example, if the NFL had not learned of the selected grantee prior to the announcement of the NGA, it is unlikely this would be an ongoing source of controversy or concern. In addition, NIH is not permitted to discuss non-public award decisions. Yet, at some point in this series of events, that no longer became a concern. Finally, NIH does not release non-funded grant applications. In this case, however, there appears to be extensive public knowledge about the details of specific grant applications that did not receive this award.

The control of confidential information is critical to the integrity of NIH's mission and decision-making process. It is important to understand the circumstances of these disclosures to

<sup>&</sup>lt;sup>87</sup> Democratic Staff Report, at 26<sup>88</sup> MOU, at 4.

ensure that NIH possesses and enforces appropriate rules, policies, or procedures to prevent unauthorized disclosures of confidential information.

5) How does NIH evaluate conflicts of interest between applicants and donors in public-private partnership grant programs such as SHRP?

There has been much speculation about whether individuals involved in these events had a clear conflict of interest due to their affiliation with the NFL and inclusion on a grant proposal to be funded by the League. There is little evidence to suggest anyone from or affiliated with the League advocated on behalf of a specific research team or grant application, especially in the events leading up to the Council meeting in September. Further, it does not appear that anyone from NIH – which, unlike FNIH, would have access to the details of the grant applications – raised concerns about conflict of interest. In fact, there is evidence to suggest that individuals from NIH reached out to some of the individuals in question to discuss this grant process.

It does, however, raise an important question about how NIH evaluates conflicts of interest between applicants and donors for grants funded through public-private partnerships. For example, the two Principle Investigators on the UNC grant were researchers who also serve as medical advisors to the NFL. While they did not ultimately receive the award, it does not appear that they were specifically excluded from the review due to their affiliation with the League.

While NIH may have clear rules and processes for evaluating these types of potential conflicts, given the controversy ignited by these events it is important to clarify how the Institutes evaluate these situations.

#### Conclusion:

It is possible the NIH acted appropriately. Perhaps the same can be argued for other parties involved. In the opinion of the Republican staff, the Committee does not have all the facts necessary to reach those conclusions. However, the questions and concerns raised by these events are vital to the integrity of research and the grant award decision-making process. While this grant award has become an unfortunate distraction from the greater issue of improving the science of traumatic brain injury (TBI), given the significant public attention to these events, it is clear that a thorough and objective review by the HHS OIG is necessary. This review is important to the strength and integrity of the SHRP, as well as the independence of NIH decision-making. Further, this controversy has tarnished the reputations of some of the leading TBI researchers and medical experts in the nation. In the interest of the millions of Americans that suffer from these injuries every year, it is critical that any judgement about their conduct be based on a complete assessment of these events.

Thank you for your prompt attention to this referral. If you or your staff has any questions, please contact John Ohly or Brittany Havens of the Committee's Republican staff at (202) 225-2927.

Sincerely,

Fred Upton Chairman Tim Murphy

Chairman

Subcommittee on Oversight and

Investigations

Joseph R. Fitts

Chairman

Subcommittee on Health

Michael C. Burgess, M.D.

Chairman

Subcommittee on Commerce Manufacturing,

and Trade

**Sent:** Tue, 16 Aug 2016 18:10:20 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Wholley, David (FNIH) [T]; Wolf-Rodda, Julie (FNIH) [T]

Subject: PACT

Hi, Francis. Hope all is well and that you are staying cool. Shortly you will get a formal note from me but I wanted to let you know ASAP that our PPP Committee has approved FNIH to proceed with PACT in full, pending successful completion of the design phase, of course. David and Stacey are already diligently working on this, so it is great to have the formal approval. All the best, M.

Sent:Wed, 28 Sep 2016 06:24:03 -0400To:Collins, Francis (NIH/OD) [E]Subject:RE: BMGF, Pfizer, AMP, PACT

Thank you so much, Francis. The most important thing is to have good attendance and that you are game to sing a song... Let me adjust the program a bit and send you the draft in a couple of days.

Between you and I, M.

From: Collins, Francis (NIH/OD) [E]

**Sent:** Wednesday, September 28, 2016 6:20 AM **To:** Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: RE: BMGF, Pfizer, AMP, PACT

Thank you! And thanks to Charlie! Now, what can I do to make the symposium as special as possible?

Francis

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, September 27, 2016 5:30 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: BMGF, Pfizer, AMP, PACT

Francis, I just spoke with Charlie and explained the situation. He was very gracious and said that he was very grateful for your presence at the symposium and understood that you needed to leave for dinner. Phew!!! Let's make the symposium really special! M.

From: Collins, Francis (NIH/OD) [E]

Sent: Tuesday, September 27, 2016 10:23 AM

To: Freire, Maria (FNIH) [T]

Subject: RE: BMGF, Pfizer, AMP, PACT

Really sorry about this situation. Current plan was to welcome students and mentors at my house at 6 PM.

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, September 27, 2016 8:21 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** RE: BMGF, Pfizer, AMP, PACT

Uh-oh is right. What a quandary, especially because of the prizes to Pfizer and the BMGF. Let me see how we can sort it out and will get back to you. What time is dinner? M.

From: Collins, Francis (NIH/OD) [E]

Sent: Monday, September 26, 2016 5:19 PM
To: Freire, Maria (FNIH) [T] < mfreire@fnih.org>

Subject: RE: BMGF, Pfizer, AMP, PACT

Hi Maria,

Uh-oh. When I read your note I realized there is a significant schedule problem – while I knew of the afternoon symposium on Oct. 19, I did not have anything on my calendar about a reception and dinner for that evening. I had made a plan more than a month ago to host a dozen students and their mentors at my house that evening. Yikes!

I'm seeking your guidance – if my presence at the evening events on Oct.19 is absolutely essential to maintain good will between NIH and FNIH, then I will try to see if the student event can be rescheduled for another evening (though that will be challenging). Can you advise?

Thanks, and sorry about this,

Francis

From: Freire, Maria (FNIH) [T]

Sent: Saturday, September 24, 2016 7:07 AM

To: Collins, Francis (NIH/OD) [E]

Cc: Steve Paul

Subject: BMGF, Pfizer, AMP, PACT

#### Confidential

Good morning, Francis. It was good to see you at Ellen's celebration - of course, everyone loved the song! A few vignettes:

First, we wanted to let you know, confidentially, that the BMGF and Pfizer have won the first Charles Sanders Partnership Awards, which we will bestow the evening of October 19th, following the symposium at NIH. We are working with Trevor and Freda to orchestrate who will come. These are on your calendar. Any chance we can get a song too - either at the symposium or at dinner?

On another note - thanks for your help on the AMP call yesterday. Much, much appreciated! The PACT meeting went well too - Stacey and David are awesome. Doug, Jim and Dinah were there so we got the NCI top brass. Good discussion, random at first and then coalesced into action items. I know David will soon or has brought you up to date on this.

Have a good weekend! M.

Sent:Tue, 27 Sep 2016 17:30:18 -0400To:Collins, Francis (NIH/OD) [E]Subject:Re: BMGF, Pfizer, AMP, PACT

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 Sent:
 Tue, 27 Sep 2016 08:20:50 -0400

 To:
 Collins, Francis (NIH/OD) [E]

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Sent: Wed, 28 Sep 2016 07:12:12 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: Re: BMGF, Pfizer, AMP, PACT

#### Ok!!!!

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, September 28, 2016 6:53 AM

**To:** Freire, Maria (FNIH) [T]

Subject: RE: BMGF, Pfizer, AMP, PACT

Happy to come up with a song, and to encourage attendance!

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, September 28, 2016 6:24 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** RE: BMGF, Pfizer, AMP, PACT

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Between you and I, M. (b) (6)

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Have a good weekend! M.

Sent: Tue, 11 Oct 2016 19:26:59 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: Re: Buffy and the Kennedy Center

I am pretty open until 3:30pm, when I have a call scheduled with Ann Lurie. The office number is 60 60 and my cell is 60 60 Either works. M.

On Oct 11, 2016, at 6:10 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Very encouraging, thanks! Crazy week, but I might be able to call tomorrow on the way to the airport – around 3 PM?

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, October 11, 2016 4:45 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Buffy and the Kennedy Center

Hi Francis,

I had a good conversation with Buffy re: Kennedy Center. She found the concept very interesting but had a bunch of semi-technical questions I could not answer. I am sure you know the answers. FYI, she has just made some donations (including underwriting Renee Fleming's projects for 2 years). She is supportive and willing to help, as needed. Happy to debrief when you have a moment. Cheers, M.

**Sent:** Fri, 7 Oct 2016 19:50:40 -0400

To: Seigel, Fred

Cc: Collins, Francis (NIH/OD) [E]

Subject: RE: Francis Collins

Just came up for air, sorry for the delay, Fred. Here is the information promised:

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health
MSC 0148
1 Center Drive
Room 118A
Bethesda, MD 20892-0148

bethesau, Mb 20052 0140

e-mail: (b) (6)

Cheers, Maria

From: Seigel, Fred [mailto:FSeigel@beaconcapital.com]

Sent: Friday, October 07, 2016 6:57 AM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: Re: Francis Collins

Maria,

Many thanks. Both addresses would be helpful. I will get a formal invitation sent on Monday.

I hope you have a wonderful weekend.

All the best, Fred

#### Fred A. Seigel | President & Chief Operating Officer | Beacon Capital Partners, LLC

200 State Street, 5th Floor, Boston, MA 02109

(b) (6)

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responsible for delivering this e-mail to the intended recipient, please be advised that you have received this message in error and that any use, dissemination, forwarding, printing or copying is strictly prohibited. Please notify Beacon Capital Partners, LLC, Beacon Capital Partners London Limited or Beacon Capital Partners France SAS, as applicable, immediately and destroy all copies of this message and any attachments. You will be reimbursed for reasonable costs incurred in notifying us. This e-mail is not intended to, and shall not, constitute an electronic signature giving rise to a binding legal contract, unless expressly stated otherwise in the body of the e-mail by the sender.

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On Oct 7, 2016, at 12:02 AM, Freire, Maria (FNIH) [T] < mfreire@fnih.org > wrote:

Dear Fred,

I just heard from Francis. This is his reply:

Hi Maria,

Since I am not sure what my schedule will look like after January 20, I have been avoiding making speaking commitments. But I'll watch for the formal invitation and see whether there is a way to work this out.

Thanks, Francis

Fred, I encourage you to send him the formal invitation. Please let me know if you need his address. It may be good to also send it via e-mail.

Cheers, Maria

Subject: RE: Georgetown Prep Grad Raises \$200,000 for NIH Cancer Research with Souped-Up Sports Car - Bethesda Beat - Bethesda, MD Indeed! We are now up to about 50,000 Facebook hits! Sooo, after Jan 7, may I buy you a cup of coffee - or glass of wine? M. ----Original Message----From: Collins, Francis (NIH/OD) [E] Sent: Friday, December 23, 2016 11:08 AM To: Burklow, John (NIH/OD) [E] (b) (6) >; Freire, Maria (FNIH) [T] <mfreire@fnih.org> Cc: Tabak, Lawrence (NIH/OD) [E] (b) (6); Linehan, Marston (NIH/NCI) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6); Fine, Amanda (NIH/OD) [E] (b) (6) Wojtowicz, Emma (NIH/OD) [E] (b) (6); Garrett, Peter (NIH/NCI) (b) (6) >; Vitelli, Cynthia (NIH/NCI) [E] (b) (6) Hatch, Shannon [E] (NIH/NCI) [E] (b) (6) >; Meltzer, Abbey (FNIH) [T] <ameltzer@fnih.org> Subject: RE: Georgetown Prep Grad Raises \$200,000 for NIH Cancer Research with Souped-Up Sports Car-Bethesda Beat - Bethesda, MD Amazing kid, amazing story, amazing Marston, amazing NIH and FNIH. Gives me one more reason to smile at this holiday. Francis ----Original Message----From: Burklow, John (NIH/OD) [E] Sent: Thursday, December 22, 2016 10:03 PM To: Freire, Maria (FNIH) [T] <mfreire@fnih.org> Cc: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Linehan, Marston (NIH/NCI) [E] (b) (6)>; Lowy, Douglas (b) (6); Fine, Amanda (NIH/OD) [E] (b) (6); Wojtowicz, Emma (NIH/NCI) [E] (NIH/OD) [E] (b) (6); Garrett, Peter (NIH/NCI) [E] (b) (6); Vitelli, Cynthia (NIH/NCI) [E] (b) (6); Hatch, Shannon (NIH/NCI) [E] (b) (6): Meltzer, Abbey (FNIH) [T] <ameltzer@fnih.org> Subject: Re: Georgetown Prep Grad Raises \$200,000 for NIH Cancer Research with Souped-Up Sports Car-Bethesda Beat - Bethesda, MD What a wonderful, inspiring story! Happy Holidays! Sent from my iPhone > On Dec 22, 2016, at 10:01 PM, Freire, Maria (FNIH) [T] <mfreire@fnih.org> wrote: > Thanks for sending this, John. It was an amazing experience to meet him and his parents - very moving. They are so, so grateful to NIH, to Marston and to the entire team. (b)(6)Wow. > Our Facebook page lit up; there were over 20,000 hits in less than 24 hours. He is a fantastic person and a terrific

Freire, Maria (FNIH) [T]

Fri. 23 Dec 2016 11:10:24 -0500

Collins, Francis (NIH/OD) [E]

From:

Sent:

To:

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spokesman for rare kidney cancer and for NIH.

Happy Holidays to all, Maria

Non Dec 22, 2016, at 9:40 PM, Burklow, John (NIH/OD) [E]

This is the state of the s
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From: Freire, Maria (FNIH) [T] Sent: Thu, 22 Dec 2016 22:01:52 -0500 To: Burklow, John (NIH/OD) [E] Cc: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Linehan, Marston (NIH/NCI) [E];Lowy, Douglas (NIH/NCI) [E];Fine, Amanda (NIH/OD) [E];Wojtowicz, Emma (NIH/OD) [E];Garrett, Peter (NIH/NCI) [E];Vitelli, Cynthia (NIH/NCI) [E];Hatch, Shannon (NIH/NCI) [E];Meltzer, Abbey (FNIH) [T] Subject: Re: Georgetown Prep Grad Raises \$200,000 for NIH Cancer Research with Souped-Up Sports Car - Bethesda Beat - Bethesda, MD Thanks for sending this, John. It was an amazing experience to meet him and his parents - very moving. They are so, so grateful to NIH, to Marston and to the entire team. Wow. Our Facebook page lit up; there were over 20,000 hits in less than 24 hours. He is a fantastic person and a terrific spokesman for rare kidney cancer and for NIH. Happy Holidays to all, Maria > On Dec 22, 2016, at 9:40 PM, Burklow, John (NIH/OD) [E] (b) (6) wrote: > > http://www.bethesdamagazine.com/Bethesda-Beat/Web-2016/Georgetown-Prep-Grad-Raises-200000-for-NIH-Cancer-Research-with-Souped-Up-Sports-Car/

> Sent from my iPhone

>

From: Freire, Maria (FNIH) [T] Sent: Fri. 23 Dec 2016 11:46:06 -0500 To: Collins, Francis (NIH/OD) [E] Subject: RE: Georgetown Prep Grad Raises \$200,000 for NIH Cancer Research with Souped-Up Sports Car - Bethesda Beat - Bethesda, MD With or without that decision, just to catch up. I have my fingers crossed. ----Original Message----From: Collins, Francis (NIH/OD) [E] Sent: Friday, December 23, 2016 11:39 AM To: Freire, Maria (FNIH) [T] <mfreire@fnih.org> Subject: RE: Georgetown Prep Grad Raises \$200,000 for NIH Cancer Research with Souped-Up Sports Car -Bethesda Beat - Bethesda, MD Possibly, but it's up to some guy in New York... ----Original Message----From: Freire, Maria (FNIH) [T] Sent: Friday, December 23, 2016 11:10 AM To: Collins, Francis (NIH/OD) [E] (b)(6)Subject: RE: Georgetown Prep Grad Raises \$200,000 for NIH Cancer Research with Souped-Up Sports Car-Bethesda Beat - Bethesda, MD Indeed! We are now up to about 50,000 Facebook hits! Sooo, after Jan 7, may I buy you a cup of coffee - or glass of wine? M. ----Original Message----From: Collins, Francis (NIH/OD) [E] Sent: Friday, December 23, 2016 11:08 AM To: Burklow, John (NIH/OD) [E] (b) (6); Freire, Maria (FNIH) [T] <mfreire@fnih.org> Cc: Tabak, Lawrence (NIH/OD) [E] (b) (6); Linehan, Marston (NIH/NCI) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6); Fine, Amanda (NIH/OD) [E] (b) (6); Wojtowicz, Emma (NIH/OD) [E] (b) (6) Garrett, Peter (NIH/NCI) (b) (6) >; Vitelli, Cynthia (NIH/NCI) [E] [E] (b) (6) Hatch, Shannon (NIH/NCI) [E] (b) (6); Meltzer, Abbey (FNIH) [T] <ameltzer@fnih.org> Subject: RE: Georgetown Prep Grad Raises \$200,000 for NIH Cancer Research with Souped-Up Sports Car-Bethesda Beat - Bethesda, MD Amazing kid, amazing story, amazing Marston, amazing NIH and FNIH. Gives me one more reason to smile at this holiday. Francis ----Original Message----From: Burklow, John (NIH/OD) [E] Sent: Thursday, December 22, 2016 10:03 PM To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

NIH - 000657

(b) (6) >; Fine, Amanda (NIH/OD) [E]

(b) (6); Garrett, Peter (NIH/NCI) [E]

(b) (6) >; Linehan, Marston (NIH/NCI) [E]

(b) (6); Tabak, Lawrence (NIH/OD) [E]

(b) (6); Lowy, Douglas

(b) (6); Wojtowicz, Emma

(b) (6) Vitelli,

Cc: Collins, Francis (NIH/OD) [E]

(NIH/NCI) [E]

(NIH/OD) [E]

| Cynthia (NIH/NCI) [E]                                                         | (b) (b); Haten, Shannon (NIH/NCI)                                | [E] (b) (b)                                 |
|-------------------------------------------------------------------------------|------------------------------------------------------------------|---------------------------------------------|
| Meltzer, Abbey (FNIH) [T] <amelta< td=""><td></td><td></td></amelta<>         |                                                                  |                                             |
|                                                                               | Raises \$200,000 for NIH Cancer Research                         | with Souped-Up Sports Car -                 |
| Bethesda Beat - Bethesda, MD                                                  |                                                                  |                                             |
|                                                                               |                                                                  |                                             |
| What a wonderful, inspiring story!                                            |                                                                  |                                             |
| Happy Holidays!                                                               |                                                                  |                                             |
| Sent from my iPhone                                                           |                                                                  |                                             |
| > On Dec 22, 2016, at 10:01 PM, Fr                                            | reire, Maria (FNIH) [T] <mfreire@fnih.org></mfreire@fnih.org>    | · wrote:                                    |
|                                                                               |                                                                  |                                             |
| > Thanks for sending this, John. It so, so grateful to NIH, to Marston a Wow. | was an amazing experience to meet him and nd to the entire team. | his parents - very moving. They are (b) (6) |
| >                                                                             |                                                                  |                                             |
| > Our Facebook page lit up; there w                                           | vere over 20,000 hits in less than 24 hours. I                   | He is a fantastic person and a terrific     |
| spokesman for rare kidney cancer as                                           | nd for NIH.                                                      |                                             |
| >                                                                             |                                                                  |                                             |
| > Happy Holidays to all, Maria                                                |                                                                  |                                             |
|                                                                               |                                                                  |                                             |
| >                                                                             |                                                                  |                                             |
| >> On Dec 22, 2016, at 9:40 PM, B                                             | urklow, John (NIH/OD) [E]                                        | (b) (6) wrote:                              |
| >>                                                                            |                                                                  |                                             |
| >>                                                                            |                                                                  |                                             |
| >> http://www.bethesdamagazine.co                                             | om/Bethesda-Beat/Web-2016/Georgetown-F                           | Prep-Grad-Raises-200000-for-NIH-            |
| Cancer-Research-with-Souped-Up-                                               | Sports-Car/                                                      |                                             |
| >>                                                                            |                                                                  |                                             |
| >>                                                                            |                                                                  |                                             |
| >> Sent from my iPhone                                                        |                                                                  |                                             |

**Sent:** Thu, 6 Oct 2016 23:46:59 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Heads up

Makes sense, Francis. By the way, he is well aware that things may be in transition but that did not worry him at all. He really hopes you can come. M.

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, October 6, 2016 11:43 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: Heads up

Hi Maria,

Since I am not sure what my schedule will look like after January 20, I have been avoiding making speaking commitments. But I'll watch for the formal invitation and see whether there is a way to work this out.

Thanks, Francis

From: Freire, Maria (FNIH) [T]

Sent: Thursday, October 06, 2016 10:40 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Heads up

Hi, Francis. Last Friday I met with Fred Siegel, who was recommended by Paul Montrone as a possible Board Member. He is terrific, actually.

(b) (6)

Fred heads Beacon Capital, a private real estate investment trust (REIT). During our conversation he mentioned they have their annual meeting every April and noted that they never have invited a speaker from the medical field. As a big fan, he wondered if you might be able to be the keynote speaker next year.

I told him I did not know but that he should send a letter of invitation directly to you. (I asked for more information and he sent the note below. The list of speakers is very impressive.) If this is not something you would consider, just let me know. Otherwise, you should be getting the formal invitation soon.

Best, Maria

Begin forwarded message:

From: "Seigel, Fred" <FSeigel@beaconcapital.com>

Date: October 3, 2016 at 12:15:38 PM EDT

To: "mfreire@fnih.org" <mfreire@fnih.org>

Subject: Dr. Collins:

### mfreire@fnih.org

Dear Maria,

It was wonderful to meet you on Friday and I am honored by your consideration of me as a potential board member. I have great admiration for the mission of the NIH and the foundation.

As a follow-up to my inquiry about Dr. Collins addressing our annual investor conference during dinner on Monday, April 24, 2017, I wanted to provide some basic information. The event will be our welcoming reception and dinner on Monday, April 24, 2017, preceding our meetings that will take place the following day. The events will take place at the Seaport Hotel in Boston.

We have a diverse group of institutional investors, including:

- Public pensions such as CalSTRS, New York State Common Retirement Fund, Oregon Public Employees Retirement Fund, State of Wisconsin Investment Board
- Corporate pensions such as GE, AT&T
- Financial service firms such as Allstate Insurance, Liberty Mutual Insurance, Erie Insurance
- Endowments such as Harvard, Cornell, Dartmouth, Northwestern, Wellesley
- Foundations such as W.K. Kellogg Foundation, Boston Foundation, Irvine Foundation, Mott Foundation. Irvine Foundation
- Non-U.S. investors such as Allianz Insurance, Ivanhoe Cambridge, Generali Insurance

We expect to have 80 to 100 people in attendance, including some of my colleagues at Beacon. Our previous speakers have included:

- Larry Summers, former Secretary of the U.S. Treasury
- Leon Panetta, former Presidential Chief of Staff, CIA Director, and U.S. Secretary of Defense
- Laura D'Andrea Tyson, former Chair of the U.S. President's Council of Economic Advisers
- Allen Sinai, Co-Founder, CEO and Chief Global Economist and Strategist at Decision Economics, Inc.
- Ken Burns, documentarian
- Doris Kearns Goodwin, historian and author
- Wes Moore, author and social entrepreneur
- Bryan Stevenson, lawyer, social justice activist, founder and executive director of the Equal Justice Initiative

I know Dr. Collins has tremendous demands on his schedule, but I think he would find this a very interesting event with an engaging audience.

Thank you again for your consideration. I look forward to speaking with you again soon.

Best regards,

Fred

**Sent:** Mon, 10 Oct 2016 19:08:07 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: birney@ebi.ac.uk

**Subject:** Re: introducing you to each other

Of course, Francis, I would be happy to do so.

Ewan, let's sort out a time that is convenient. This week is better - the next few weeks are pretty bad.

Cheers, Maria

From: Collins, Francis (NIH/OD) [E] Sent: Monday, October 10, 2016 7:04 PM

**To:** Freire, Maria (FNIH) [T] **Cc:** birney@ebi.ac.uk

**Subject:** introducing you to each other

Hi Maria,

Ewan Birney, the Director of EMBL-EBI (see <a href="https://www.ebi.ac.uk/about/people/ewan-birney">https://www.ebi.ac.uk/about/people/ewan-birney</a>), has recently (though not yet publicly) agreed to serve as the Chair of the Steering Committee for the Global Alliance for Genomic Health (aka GA4GH, see <a href="http://genomicsandhealth.org/about-global-alliance">http://genomicsandhealth.org/about-global-alliance</a>). I have known Ewan for almost 20 years. He is an awesomely creative leader. He played a significant role in the success of the Human Genome Project, and led the follow-on epigenomics project known as ENCODE.

In a phone conversation today, the future of GA4GH came up. It currently exists as an MOU between the Broad Institute, the Ontario Institute for Cancer Research, and the Sanger Institute. Apparently it does not have independent non-profit status. But for the vision of GA4GH to be realized, the organization needs to be able to raise a modest amount of its own funds – from funding agencies like NIH, and maybe also from philanthropy. I couldn't see how this could happen unless GA4GH had its own legal status. Ewan was concerned about what this would mean in terms of lawyers, bylaws, choosing a location for incorporation, etc.

I volunteered YOU as someone who might be able to provide some insight on these issues, given your past history with NIH, the TB Alliance, the Lasker Foundation – and your very important present role as President and Executive Director of the Foundation for NIH. Would you be willing to engage with Ewan (cc'd here so you can capture his e-mail address) with some very expert advice about the pros and cons of various future options for GA4GH?

Many thanks, Francis

 Sent:
 Sat, 3 Dec 2016 11:38:38 -0500

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Burklow, John (NIH/OD) [E]

Subject: Re: Key Republicans urge Trump to keep Francis Collins as NIH director

You should be very pleased with the well-deserved support! It would be good to have key academics join in...

On Dec 3, 2016, at 11:35 AM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Yeah, pretty amazing. The letter is attached and seems to have gone viral rather quickly.

From: Freire, Maria (FNIH) [T]

Sent: Saturday, December 03, 2016 11:19 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Burklow, John (NIH/OD) [E] (b) (6)

Subject: Fwd: Key Republicans urge Trump to keep Francis Collins as NIH director

Francis, in case you had not seen this. M.

Article in Stat today.

Key Republicans urge Trump to keep Francis Collins as NIH director

WASHINGTON — In a letter sent Friday, top congressional Republicans urged President-elect Donald Trump to keep Dr. Francis Collins as director of the National Institutes of Health.

Collins received the endorsement from key GOP members of Congress: outgoing House and Energy Commerce chairman Fred Upton, Senate health committee chairman Lamar Alexander, and the two chairmen of the appropriations committees that oversee NIH: Senator Roy Blunt of Missouri and Congressman Tom Cole of Oklahoma.

"Dr. Collins is the right person, at the right time, to continue to lead the world's premier biomedical research agency," they said in the letter.

Trump has made few comments on NIH, aside from a 2015 remark that he had heard "terrible" things. But many in Washington have speculated since the election that Collins could end up staying on under Trump.

The agency is in the midst of launching several major research efforts, including the Precision Medicine Initiative and Vice President Joe Biden's cancer moonshot. Collins, who has served as director since 2009, has been instrumental to those programs.

The only other known contender for the job is Congressman Andy Harris of Maryland, a Republican who <u>has openly lobbied for the job</u> in the past few days. But a lobbyist who works on medical research policy told STAT on Friday that even other Republicans on the Hill might prefer to see Collins stay in the role.

The letter sent to Trump on Friday seems to confirm that.

"Dr. Collins has a scientific vision. You can agree or disagree with it, but that was his perspective as a leader," said the lobbyist, who spoke on the condition of anonymity to discuss the matter. "He's worked with the [Obama] administration to come up with big initiatives to capture the imagination."

<CongressLetterNIHDirector.pdf>

 Sent:
 Fri, 9 Sep 2016 06:01:36 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Re: My Northwestern Medicine for September 7, 2016

Thanks for the nice note to Ann, Francis.

This reminds me that I have some nice pictures of you at the Award ceremony, especially a couple with Jeannie Lee. I've had them on my folder for you but we have not had a chance to meet since May.

On another topic, I recently mentioned to John Burklow that we are pleased to help garner support for your portrait. Happy to chat or he can fill you in.

Cheers, M.

**From:** Collins, Francis (NIH/OD) [E] **Sent:** Friday, September 9, 2016 5:40 AM

To: Ann Iurie

Subject: RE: My Northwestern Medicine for September 7, 2016

Dear Ann,

Thanks for your note. I had a great visit to Northwestern and the University of Chicago with Senator Durbin. The schedule was tight so I didn't get a complete tour of Lurie Childrens – but what I saw was very beautiful, welcoming, and impressive. I met with four sets of parents who had lost a child to cancer, and we discussed some of the new approaches that are being taken to finding cures for pediatric cancer – some of which were featured in Wednesday's announcements about the Cancer Moonshot (see <a href="http://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel">http://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel</a>).

(b) (6)

All the best, Francis

**From:** Ann lurie [mailto:ann@annlurie.com] **Sent:** Wednesday, September 07, 2016 1:10 PM

**To:** Collins, Francis (NIH/OD) [E]

Subject: Fwd: My Northwestern Medicine for September 7, 2016

Dear Dr. Collins,

Thank you for your visit to Northwestern. I'm thrilled to hear funding for medical research will increase! I understand you were also scheduled for a tour of Lurie Childrens. I hope you were favorably impressed. Apologies I was not able to participate.

(b) (6)

(b) (6)

Best wishes. Sincerely,

Ann Lurie

Ann Lurie Lurie Holdings 2 N Riverside Plz Suite 1240 Chicago, IL 60606

Begin forwarded message:

From: Feinberg School of Medicine < med-connections@northwestern.edu>

**Date:** September 7, 2016 at 9:35:22 AM MDT

To: ann@annlurie.com

Subject: My Northwestern Medicine for September 7, 2016

Reply-To: med-connections@northwestern.edu

Having trouble viewing this email? View as Webpage

## My Northwestern Medicine

September 7, 2016

NIH Director Visits Northwestern to Discuss Research Funding



National Institutes of Health Director Francis Collins and Illinois Sen. Dick Durbin spoke to an auditorium of nearly 300 physicians and researchers at Northwestern about the critical importance of sustaining momentum in medical research funding.

## Read more »

# Using Human-Centered Design to Create Better Healthcare Models in Kenya

Fourth-year medical student Claudia Leung spent the past year in western Kenya doing research and developing a healthcare model for patients with chronic diseases.



# Northwestern Medicine Specialty Pharmacy Expands Its Reach

The pharmacy's single location downtown offers services across the system to benefit patients both next door and miles away.

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## Cardiac Stem Cells Predict Drug Safety and Efficacy

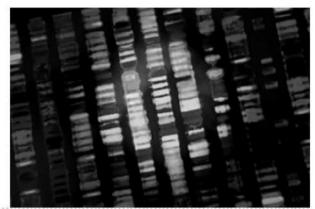
Analyzing a patient's own stem cells can predict the safety and efficacy of drugs that have the potential to damage a patient's heart, according to a new study.

## Read more »



## Accelerating Precision Medicine for African American Patients

Northwestern Medicine scientists have received a \$7.5 million grant to study how genetic information from African American patients can predict their response to medications.



### Read more »

Have an idea for the newsletter or a comment on this issue?

## Contact Us »



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Feinberg School of Medicine, 420 East Superior Street, 12th Floor, Chicago, IL 60611

SafeUnsubscribe™ ann@annlurie.com

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Sent by med-connections@northwestern.edu

**Sent:** Wed, 14 Sep 2016 21:37:21 -0400

To: Collins, Francis (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E]

Cc: Tabak, Lawrence (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Burklow, John

(NIH/OD) [E]

Subject: Re: NFL

No, I have not been in contact with them. M.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, September 14, 2016 9:34 PM

To: Koroshetz, Walter (NIH/NINDS) [E]; Freire, Maria (FNIH) [T]

Cc: Tabak, Lawrence (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: NFL

https://www.washingtonpost.com/news/sports/wp/2016/09/14/nfl-to-launch-new-100-million-concussion-initiatives-to-improve-player-safety/

Anyone know how NFL plans to spend this newly announced \$40M for research on "neuroscience"?

**Francis** 

**Sent:** Thu, 17 Nov 2016 15:01:12 -0500 **To:** Collins, Francis (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]

Subject: RE: Request

## Thank you!

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, November 17, 2016 2:55 PM
To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Cc: Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E]

(b) (6)

Subject: Re: Request

Sure! Looping in Ayanna and Gretchen

Sent from my iPhone

On Nov 17, 2016, at 12:01 PM, Freire, Maria (FNIH) [T] < mfreire@fnih.org > wrote:

Hi Francis! We are meeting tomorrow for a catch up and then with others on NFL. Would it be possible to find 5 minutes for us to chat one-on-one? It should not take more than that. Thanks, M.

**Sent:** Tue, 18 Oct 2016 21:30:18 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Sanders Symposium TOMORROW

## Thanks, Francis!

**From:** Collins, Francis (NIH/OD) [E] **Sent:** Tuesday, October 18, 2016 9:29 PM

**To:** Icddir-l@list.nih.gov **Cc:** Freire, Maria (FNIH) [T]

Subject: Sanders Symposium TOMORROW

### Dear colleagues,

Tomorrow October 19 from 4-5:30 PM in the Porter Neuroscience Center, there will be a scientific symposium honoring Charlie Sanders, MD, who has served as Chairman of the Board of the FNIH for the last 20 years and is now retiring. World class speakers include three Lurie Prize winners: Karl Deisseroth, Jeannie Lee, and Ruslan Medzhitov. There will be a reception at 5:30 PM.

I am concerned that some of you and your colleagues might not be aware of this special event – so please spread the word. More information can be found at http://www.fnih.org/what-we-do/current-lectures-awards-and-events/sanders-scientific-symposium

Best, Francis

 Sent:
 Thu, 17 Nov 2016 12:01:55 -0500

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Request

Hi Francis! We are meeting tomorrow for a catch up and then with others on NFL. Would it be possible to find 5 minutes for us to chat one-on-one? It should not take more than that. Thanks, M.

**Sent:** Fri, 14 Oct 2016 18:59:12 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Koroshetz, Walter

(NIH/NINDS) [E];Burklow, John (NIH/OD) [E] **Subject:** Trump on Concussions

In case you missed this, M.

 $\underline{http://www.espn.com/nfl/story/\_/id/17785146/donald-trump-republican-presidential-candidate-criticizes-softer-nfl-rules-concussions$ 

 Sent:
 Wed, 12 Oct 2016 15:38:04 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Yup

It would work. Limited funds but let me know... Safe travels! M.

 Sent:
 Mon, 11 Dec 2017 22:41:39 +0000

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 McManus, Ayanna (NIH/OD) [E]

Subject: Check presentation on 12-13 for kidney cancer research

Hi Francis. Tomorrow and Wednesday's meeting on opioids ought to be very interesting and hopefully will help move the needle. Fingers crossed!

I am told that you will come to the FNIH Open House on Wednesday – that is awesome! Just in case, we will have a small "check-handing" ceremony of an additional contribution of \$100,000 by *Driven to Cure* to FNIH at 4:30pm. It would be great if you could be there – although we know well no NIHer can actually "receive" the oversized check (we are very careful about that!). The funds will go to support Marston Linehan's research.

You may recall that *Driven to Cure* is the organization that donated \$200,000 last year for Marston's research. It was founded by Andrew Lee,

Andrew is passionate about cars and takes his orange Nissan GTR to car events all over the USA, raising awareness and funds for kidney cancer research. Here is a link to his story, which has great shout-outs for NIH: <a href="https://www.driventocure.org/programs.html">https://www.driventocure.org/programs.html</a>

Andrew and his family and Marston will be there. I have not heard from Jim Gilman yet. Any chance you can be there? Cheers, M.

**Sent:** Tue, 15 Aug 2017 16:29:34 +0000 **To:** Collins, Francis (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]

Subject: David Trone Candidacy

Attachments: David Trone candidacy.docx, The opioid crisis hits home for Maryland man -

DTrone\_BSun.docx

Francis, in case you missed it, David has announced his run for Congress for the 6<sup>th</sup> district. Increased support for NIH is at the top of his platform and he is keenly interested in opioids (highlighted in the attached). He recently shared that his nephew died of an opioid overdose. His editorial in the Baltimore Sun is also attached. I am meeting with David in a couple of weeks. Best, M.

## DAVID TRONE ANNOUNCES CANDIDACY FOR CONGRESS IN MARYLAND'S 6TH DISTRICT

Contact: Alex Koren (alex at davidtrone.com)

Potomac, MD (August 2, 2017) – Local entrepreneur and philanthropist David Trone announced his candidacy for the Democratic nomination for Congress in Maryland's 6th District today in a video posted on his website DavidTrone.com.

In his announcement, Trone pledged to continue the work of Congressman John Delaney, who recently announced that he will not seek re-election. "John is a good friend and a great Representative," said Trone. "With your help I'll pick up right where John leaves off."

Trone detailed his opposition to Trump administration policies, saying that he would oppose attempts to gut healthcare, women's rights, education, environmental protections, and Social Security. "This isn't a time to stand on the sidelines," said Trone.

He went on to emphasize that "fighting to protect things isn't enough" and laid out a positive agenda that includes increasing funding for the National Institutes of Health, infrastructure improvements including I-270 and I-81, and creating jobs in every part of the 6th District.

Trone also emphasized the need to help people in rural parts of the 6th District. He grew up on a family farm cleaning hog and chicken pens, and showing animals as a member of the 4H. His family struggled to keep the operation afloat, and the farm eventually went bankrupt. "I grew up on a family farm and I understand their challenges, and I'll fight to protect that way of life," said Trone.

Pledging to represent only the interests of the 6th District and to not be influenced by special interests, Trone said that he won't take money from corporations, PACs, or lobbyists. "I don't want to be their Congressman, I want to be yours."

Trone highlighted his experience creating over 6,000 jobs at Total Wine & More, a company he grew from one store to 172 stores in 22 states. Over 500 work at the company headquarters in Bethesda. He shared his belief that "life's purpose is to make things better" and emphasized his record of doing that in business. Total Wine & More has some of the highest wages and best benefits in the retail industry. They also invest in team members by paying for them to earn their GEDs and have a pilot program that offers a four-year college degree paid for by the company.

Trone and his wife June are celebrating their 30th year of marriage. Their four children are young adults.

The Trone family has an extensive record of charitable giving. Over the last three years alone, Total Wine & More's charitable donations totaled almost \$20 million to 7,000 local organizations. David, and his wife June have donated millions more through their foundation, including a recent contribution to Suburban Hospital in Montgomery County to help expand treatment for mental health and addiction.

The family has also been among the largest supporters of the ACLU for over 20 years. In recognition of David and June's longtime support, the ACLU created the Trone Center for Justice and Equality.

David and June also established a legal assistance fund for people impacted by Trump's travel ban targeting Muslims. In announcing the fund, ACLU Executive Director Anthony Romero said, "David's dedication to protecting our rights is in stark contrast to the Trump administration's attacks on liberty."

More information about David Trone and his campaign for Congress can be found at DavidTrone.com.

The opioid crisis hits home for Maryland man – BaltimoreSun.com

6/14/2017

Reporter Andrea McDaniels on why health and law enforcement officials around the state are bracing for a potential uptick in drug overdoses as a synthetic opioid has hit Maryland streets. It's so strong a dose the size of a grain of salt can kill a person. (Baltimore Sun video)

### **David Trone**

In the final days of 2016, a North Carolina halfway house called to say my nephew was missing. It wasn't the first called I'd gotten about Ian. He was like our fifth child and the focus of my attention for many years. We were in touch regularly, and he went with us on vacations and to ballgames.

Ian was a drug addict. We made sure he had access to the best doctors, residential and out-patient recovery programs, counselors and halfway houses. We worked with lawyers and parole officers to deal with his legal problems. We arranged for him to live at the halfway house and work in Asheville, N.C., because one of our daughters lives there.

We did everything we knew to do — and everything experts told us to do — but it wasn't enough. After several days of searching, Ian was found in a hotel room. He was alone, dead from an opioid overdose.

### What's This?

My story is not unusual. In 2015, the most recent year for which the Centers for Disease Control have issued official data, <u>52,404 Americans</u> died from drug overdoses, an all-time high. A recent CDC study suggests official statistics underestimate the number of opioid-related fatalities.

Overdose deaths now outnumber deaths from auto accidents and guns; only heart disease, stroke and cancer account for more deaths. Eight of every 10 drug-related deaths are due to opioids. The opioid category includes heroin and synthetic fentanyl — a combination of which killed Ian — but also legal pain medications. In fact, prescription drugs now account for more deaths than illicit ones.

As a <u>story</u> in The Sun last week detailed, the devastating impact of the opioid epidemic is hitting Maryland as well: 2,089 Maryland overdose deaths in 2016, a 66 percent increase from the year before. Overdose deaths have increased for six straight years, and have increased 300 percent since 2010.

Opioids account for an average of four deaths per day in the state. This scourge spares no one. In Montgomery County, the wealthiest county in Maryland, opioid-related deaths in 2016 were 40 percent higher than the year before.

Baltimore City health commissioner, Dr. Leana Wen, discusses the purpose of creating an online training and certification for naloxone. (Barbara Haddock Taylor, Baltimore Sun video)

Government at all levels is struggling to react as elected officials in both parties are coming to understand that addiction should be treated as a medical issue rather than a criminal issue. Restrictions have been placed on prescriptions for opioid-based pain killers. Naloxone, a lifesaving drug that reverses the effects of opioid overdoses, has been made more widely available for use by first responders. Funds for public education and treatment have been increased.

Shortly before Ian's disappearance, I was shocked to learn that most hospitals will not admit patients who merely want to detox. To fill the gap, many locales are creating detox centers where addicts can detox without fear of arrest and can be referred to professional services.

Unfortunately, these useful steps to eradicate this epidemic are colliding with politics, particularly in the Trump administration. Their budget proposal would <u>cut 95 percent</u> of the funding for the Office of National Drug Control Policy, the office empowered to tackle the opioid crisis. Their health care plan would <u>eliminate</u> Obamacare's requirement for including treatment in basic policies.

The War on Drugs has been such an abject failure — the get-tough approach having served to crowd prisons with non-violent offenders who are disproportionately African-American while having little to no discernible impact on actual narcotics use — that the country's elected leaders seemed to have...

The War on Drugs has been such an abject failure — the get-tough approach having served to crowd prisons with non-violent offenders who are disproportionately African-American while having little to no discernible impact on actual narcotics use — that the country's elected leaders seemed to have...

Reversing Mr. Obama's enforcement policies, as the administration proposes, will send addicts to jail rather than treatment. This will not help and neither will their belief that treatment and enforcement are best left to the states. In Maryland, only one emergency treatment center was funded rather than the 10 that were proposed.

Even less is being done to confront mental illness, which is closely related to drug abuse. Suicide is on the rise, and now ranks as one of the top three causes of death among Marylanders under 35. Mental health issues receive much less attention than the opioid crisis. In many ways, it is a silent epidemic. And it is deadly.

These crises have stimulated action in the private sector. For example, pharmaceutical companies are expanding efforts to create non-addictive pain treatments. Private foundations, including our family foundation, are helping local health care providers expand mental health and addiction treatment.

But more — much more — is needed, especially by government. Suicide and drug-related deaths are killing our young people, decimating their families, and robbing all of us of their future. Many of those living with addiction are struggling to survive, unable to lead the healthy and productive lives we all want.

We are not living up to our responsibilities as human beings or citizens if we allow these epidemics to go unchecked.

David Trone (dtrone@totalwine.com) is the founder of Total Wine & More, the largest private wine retailer in the country, with 172 stores in 22 states, almost 6,000 employees and headquarters in Bethesda, Md.

Sent: Tue, 18 Jul 2017 11:59:43 -0400

To: Steve Paul (b) (6) bloomgardenk@ruderfinn.com;Buffy

Cafritz; Donovan, James

(james.donovan@gs.com) (b) (6) ;tom@mindstronghealth.com;Judy Kovler

(b) (6); Ronald Krall; Freda. Lewis-Hall; Edison. Liu@jax.org; Joel Marcus; Steve Mayer; Charles,

Tracey;marty@amedconsulting.com (b) (6);Max Coslov;Lori Franklin

(b) (6); Seigel, Fred; esigal2; Sol Snyder (ssnyder@jhmi.edu); Nina Solarz; Steenberg, Russell; Stoffels, Paul [JJCUS] (PStoffe4@its.jnj.com); Thier, Samuel

Osiah, M.D.; LBrady@drexelmed.edu; Ann lurie; john.porter@hoganlovells.com; Collins, Francis (NIH/OD)

[E] (b) (6)

Cc: James, Stephanie (FNIH) [T]; Wholley, David (FNIH) [T]; Wolf-Rodda, Julie (FNIH) [T]; Klock, Kevin (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Balthaser, Robert (FNIH) [T]; Burklow, John (NIH/OD) [E]; Goldie, Christina (FDA/OC)

**Subject:** FNIH receives Charity Navigator's top rating!

Dear Members of the FNIH Board of Directors,

It is with great pleasure that I let you know that we have just been informed by Charity Navigator, America's largest independent charity evaluator, that once again the FNIH has received a **4-star rating** (the highest it bestows) AND that we are the **#1 ranked charity among Biomedical Research Organizations**.

FNIH is featured on the Charity Navigator website under  $\underline{4\text{-star charities}}$ . Please be on the lookout for an e-blast about the news and help us spread the word far and wide.

Thank you for all your help and support; we could not have done it without you!

All the best, Maria

Sent: Sat, 18 Nov 2017 01:28:11 +0000
To: Collins, Francis (NIH/OD) [E]
Cc: Burklow, John (NIH/OD) [E]
Subject: FNIH won a Gold Stevie Award!

Just now in NYC for Organization of the Year - Government or Non Profit- More than 10 Employees! Sooo honored!!!



 Sent:
 Sat, 15 Jul 2017 10:37:39 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Following up

Francis, did you get a chance to talk to Larry and Carrie about support for the gift fund, if the opportunity arises? Best, M.

**Sent:** Tue, 5 Sep 2017 21:12:04 +0000 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** Fwd: BioCentury on biopharma's social contract

Attachments: BTS2017.pdf, ATT00001.htm

Francis, in case you did not see this. It is a very interesting read! M.

Begin forwarded message:

From: "Steve Usdin" <<u>susdin@biocentury.com</u>>
To: "Freire, Maria (FNIH) [T]" <<u>mfreire@fnih.org</u>>
Subject: BioCentury on biopharma's social contract

Maria, I thought this might be of interest.

Hope all is well, Steve

Steve Usdin
Washington Editor, BioCentury
Susdin@BioCentury.com

Tel. 202-462-9582 Mobile (b) (6)

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**BACK TO SCHOOL** 

## BREACH OF CONTRACT

Merck & Co. Inc. Chairman and CEO Kenneth Frazier's resignation in August from a White House advisory council was an act of principle, and a reminder that 30 years ago Merck was one of the most respected companies in America.

Few pharma executives or members of the public remember that former Merck CEO and Chairman Roy Vagelos pledged in 1990 to cap drug price increases at or below the rate of inflation, and later warned that high launch prices could destroy public faith in the industry.

When President Donald Trump fired back with a tweet that Frazier would now have time to "LOWER RIPOFF DRUG PRICES!" he sought to deflect attention from the reasons for Frazier's resignation to a much more popular theme: disdain for drug companies. Trump knew that most Americans would applaud his attack on drug prices.

Trump's comfort in using Merck as a shield against the outrage sparked by his response to the violence in Charlottesville shows the dire state of the drug industry's reputation. And this sorry state of affairs exemplifies the breakdown of the social contract between the drug industry and the society it is supposed to serve.

Why this contract exists, and why the drug industry must repair its relationship with society, is the subject of BioCentury's 25th Back to School essay.

At the most basic level, the social contract starts with the idea that industry's sole purpose isn't to sell pills and vials, or to increase shareholder value, but to help patients live better and longer.

When the public believes drug companies are honoring the contract, governments and philanthropies are willing to fund biomedical research that leads to knowledge that industry can translate, via gigantic and risky investments, into medicines. Society will



BIOCENTURY & THINKSTOCK

pay enough for medicines to ensure that companies can attract the investment that is required to fund a long, uncertain R&D process. Governments provide strong, science-based regulation and well-defined IP protections with the explicit understanding that monopolies will end at prespecified times. And patients willingly participate in risky clinical trials for the greater good.

These contributions from society and individuals create obligations for drug companies.

Drug developers must make the investments required to produce medicines that help patients improve their health, and in the process pave the way for broad advances in public health and prosperity.

Medical product manufacturers are obliged to abide by science-based regulations, and release their grasp on captive markets when exclusivity periods terminate.

Above all, for the contract to work, patients must have access to medicines that will improve their lives at prices they can afford. And patients must believe the companies that create and sell medicines are on their side.

Judged against these criteria, the drug industry is failing despite its lip service to these obligations.

It would be wrong to suggest drug companies are solely responsible for this debacle. The greatest unmet medical need is access to affordable healthcare, and on this criterion, evidence of the broken social contract is everywhere.

The poor reputation of insurance companies, hospitals and, on some metrics, even healthcare providers, at least in the U.S., reflects the widely held view that the healthcare system is not working in the public's favor.

Moreover, the drug industry is entitled to shine a light on profitsbefore-patients behavior by insurance companies, PBMs, hospitals and physicians. They all are culpable in making healthcare unaffordable and inaccessible.

But drug companies are not helping themselves by only trying to deflect the blame for high drug prices and denial of access to the other healthcare players, or by trumpeting *ad nauseam* that other healthcare expenses account for the vast bulk of spending on public health. These arguments are irrelevant to the patient who cannot afford a necessary drug.

Anyone who is or knows a patient who is unable to obtain medicines, or who is appalled by the price of the drug they have been able to obtain, has concluded the drug industry is not holding up its end of the deal.

That sense of unfairness is leading politicians around the world to look for ways to squeeze pharma profits and weaken IP protection for the industry's products.

This year, Back to School contends that drug manufacturers, their managers and their boards of directors must acknowledge they are part of the problem, and change course.

To fulfill the social contract, Back to School argues that drug companies must stop making choices that belie the industry's claims that it puts patients first.

They must align management incentives with patient and public health, not just shareholder returns.

And most importantly, drug companies must be seen to be improving access to medicines.

Although fulfilling the social contract is almost entirely the responsibility of individual companies, the drug industry collectively needs to agree and adhere to best practices and principles on pricing, access and transparency — because the reputations of companies that do a good job of meeting their commitments to patients and society are dragged down by those that violate the contract. Some steps can only be accomplished, or will only be equitable, if there is a collective commitment.

Only if industry and its companies take aggressive, visible steps to solve access problems will they be acknowledged for creating new drugs that improve public health. And only then will they have properly earned the right to ask for society's continued investment in medical innovation and for society to pay for innovative drugs based on the value they create.

### THE SITUATION

The biopharma industry relies on government policies to fuel innovation, including science-based regulatory systems; strong but finite IP

protections; and public investment in scientific research coupled with policies that facilitate uptake of that research by the private sector.

Medical product development also relies heavily on support from individual patients and patient organizations, as participants in risky and often painful clinical research, as advocates for efficient regulatory and compassionate coverage policies, and eventually as consumers.

Giving term-limited monopolies to biopharma innovators for novel medicines, paying premium prices for novel innovative drugs, investing tens of billions of dollars annually for biomedical research and putting individual patient lives on the line in clinical trials represents an enormous investment by society (see "Cutting the Check" & "Footing the Bill").

In return, society rightfully expects the drug industry to apply its unique abilities to turn scientific advances into drugs that improve individual and public health outcomes.

Over the past three decades, the biopharma industry in fact has delivered extraordinary advances in medicine. These include transforming AIDS from a pandemic killer to a manageable disease and developing vaccines that prevent cervical and other HPV-related cancers.

The idea that a pill can prevent a disease like cystic fibrosis from choking the life out of a child, or banish HCV from someone's body is nothing short of astounding. inhibitor gamble that the cancer will stay in remission if they skip their pills for a few weeks.

In other parts of the world, many patients don't get as far as a pharmacy. In rich countries, governments routinely decide it's simply too expensive to offer their citizens some drugs that enhance and save lives. In poor countries, ordinary people don't consider purchasing medicines that people in the U.S., Europe and Japan wouldn't think of doing without.

The fact that most drug companies live up to most of their commitments to society most of the time is not good enough: partial success is perceived as total failure.

"The fact is that too many people can't afford the medicines that they need," FDA Commissioner Scott Gottlieb told Congress in July.

### THE PATH FORWARD

Society will withdraw its support if there is a consensus that drug companies aren't living up to their end of the deal. This is already starting to happen in the U.S., where some states have passed R&D transparency and anti-price gouging laws, some have introduced bills that include price caps, and efforts to impose price controls are gaining momentum. All of these measures are based on the notion that the public needs to be protected from predatory drug companies.

## PATIENTS MUST BELIEVE THE COMPANIES THAT CREATE AND SELL MEDICINES ARE ON THEIR SIDE.

There is evidence that Kymriah tisagenlecleucel from Novartis AG, which on Aug. 30 became the first CART cell therapy to gain FDA approval, can cure some leukemia patients whose disease would have been fatal. And industry's pipeline contains many more potential cures.

Ironically, the more successful the drug industry has been in producing important medicines, the lower it has sunk in public perception.

According to a September 2016 Kaiser Family Foundation poll, only 56% of Americans believe that prescription drugs developed over the past 20 years have made the lives of people in the U.S. better. That's down from 73% in March 2008.

The 2016 Harris Poll Study of Reputation Equity and Risk Across the Health Care Sector paints a worse picture. Pharmaceutical and biotech companies are in last or second-to-last place compared with hospitals, providers and insurers on reputation, putting patients first, making a positive difference and socially responsible behavior (see "Opinion Poll").

The drug industry's huge achievements have been drowned out by reports that in the U.S. some patients buy groceries for their families instead of picking up their insulin. That women and men hobbled by rheumatoid arthritis forgo biologic drugs that could make their lives tolerable. And that leukemia patients whose lives were saved by a tyrosine kinase

In Washington, heavily funded lobbying efforts to influence the political process only have produced a stalemate. Drug companies can often block laws, but have had limited success in advancing a positive agenda that is visible to the public.

Some of the industry's top legislative priorities have stalled because they are widely perceived as efforts to improve the financial health of biopharma companies rather than help patients.

For example, the biopharma industry has failed to persuade Congress to either exempt drug patents from, or modify the standards for adjudicating approved patents under the *inter partes* review system. Abuses of IPR pose an "existential threat" to the biopharma industry, according to a letter by BIO President and CEO Jim Greenwood that BioCentury published June 1.

BIO's concerns about the potential for IPR to scare off investment or unfairly invalidate valid patents may be overstated. Nonetheless, the industry's inability to persuade Congress to move on a top-priority issue is telling.

Industry also lost battles to block right-to-try legislation in 37 state legislatures. The U.S. House of Representatives soon is likely to pass an RTT bill that the Senate passed in August. While the laws do not compel companies to provide access to drugs, they are part of an antiregulatory agenda that seeks to weaken, or in this case circumvent, FDA oversight.

They likewise are an expression of public exasperation with difficulty accessing medicines.

That said, there have been some notable successes as governments seek ways to encourage drug companies to keep pursuing the search for treatments. One example is EMA's adaptive licensing pathway, which seeks to enable swift approval of drugs for limited populations based on smaller than usual data sets followed by label expansions based on data including real-world evidence. Japan's Sakigake accelerated approval pathway, coupled with reimbursement incentives for innovative drugs, is another (see "Japan's Innovation Pothole").

In Washington, the past year has seen political, industry and regulatory agreement on provisions in the 21st Century Cures Act and FDA user fee reauthorization legislation that could streamline and modernize medical product development.

Made possible by close collaboration with regulators and patients, these successes point to a winning formula: explicitly coupling policy proposals to benefits for individual patients and public health.

What won't work is abdicating responsibility by pointing fingers and devising ever more exquisitely crafted attacks on payers, PBMs and health technology assessment agencies.

Neither are exhortations to "go boldly," reminders that "time is precious," or any other advertising slogans going to cut it.

To restore public confidence and justify society's continued investment, biopharma companies must abide by - and be seen abiding by - the social contract.

First, the industry must make choices that put patients first.

Second, companies must publicly align management incentives with patient and public health, not just shareholder returns.

Third, and most obvious, drug companies must be seen improving access to medicines.

### **BAD CHOICES**

To fulfill the social contract, Back to School argues that drug companies must stop making choices that belie the industry's claims that it puts patients first.

The drug industry has made its own bed of thorns through a host of CHOICES that violated the social contract. If it wants to restore its standing in society, the industry will have to make different choices. The alternative is accepting the consequences of the choices it has made.

The most difficult choice is between duty to patients and the fiduciary duty that CEOs and boards have to their shareholders. Back to School does not argue fiduciary duty is not real, or that it is not a legal reality. But prioritizing shareholders over patients ultimately is self-destructive and thus ruinous to the creation of long-term value for shareholders.

Almost no one, even inside the industry, believes that any nation has the financial ability to pay for the increasing number of breakthrough treatments under today's pricing paradigm. This means companies are trapped between shareholder demands for continued extraordinary yield, primarily dividends and capital buybacks, and society's inability — and now unwillingness — to pay the prices required to keep the yield engine humming.

### CUTTING THE CHECK

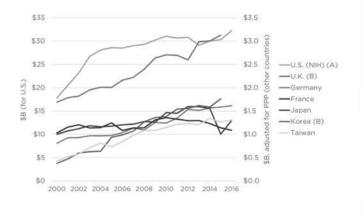
While government spending on R&D for public health has leveled off in this decade, society's investment in the life sciences remains significant. The U.S. is by far the global leader, with the **NIH** investing \$303 billion over the past 10 years.

According to data from the **Organization for Economic Cooperation and Development** (OECD), government budget appropriations or outlays for R&D (GBAORD) for the U.K. totaled \$26.5 billion, while Germany invested \$13.9 billion and France \$12.3 billion.

Asian healthcare-related R&D spending is quickly catching up to and surpassing that of continental Europe. Korea invested \$14.1 billion, while Japan spent \$13.7 billion and Taiwan \$11.9 billion.

OECD data are not available for China. However, the Chinese government committed to invest \$309 billion in science and technology between 2011 and 2015 as part of its 12th five-year plan, and consultancy **ChinaBio LLC** estimates the country dedicated over \$200 billion to life sciences during the period. ChinaBio estimates the government's 2016 investment in life sciences at more than \$100 billion, and expects the 2017 figure to surpass \$100 billion as well.

Below, OECD GBAORD figures for selected countries (right axis) are plotted against NIH actuals (left axis). GBAORD figures focus on the socio-economic objective of "health" and therefore may underrepresent spending on basic life science research. OECD figures adjusted to 2010 dollars and purchasing power parity (PPP). (A) Fiscal year ended Sept. 30; (B) 2016 GBAORD data not available; Sources: NIH; OECD



Some pharma CEOs, however, continue to defend the status quo. In March, Pfizer Inc. Chairman and CEO Ian Read said in remarks at the National Press Club, "Overall, I think it is fair to say we are being responsible when it comes to the pricing of our medicines. We are producing great value for society and simultaneously taking large financial risk."

As justification, he cited familiar tropes about the high cost of R&D, long timelines, low success rates and the small proportion of healthcare expenditures accounted for by drugs.

Read argued that, contrary to public perceptions, pharma is not a very profitable industry. "Our return on capital as an industry is around 11%," a figure that he said is "not that healthy."

BioCentury asked, but Pfizer did not answer, whether Read's position has since changed.

The drive to prop up shareholder returns has led pharma companies to make choices that violate the social contract.

First among these choices is flattening the rate of spending on R&D.

The biggest pharmas consistently return more capital to yield-seeking investors than they spend on R&D. The combined value of dividends and buybacks has outpaced R&D investment over the past decade at \$403 billion for the former to \$389 billion for the latter (see "Follow the Money).

Back to School acknowledges this is not wrong in and of itself, as long as patients also are benefiting from the industry's investment in innovation. But when drug companies flatten spending on R&D to maintain the payout to shareholders, management and boards have lost the right to say their top priority is innovation in the public interest.

Companies and their trade groups may continue to claim that investors won't fund risky R&D without these extraordinary returns, but so far the data refute the claim: investors have plowed unprecedented sums into biotech over the past 10 years – more than \$365 billion — even as the drug pricing storm mounted.

In any case, the public has heard and rejected that argument.

Companies have even less defense for other profit-boosting choices.

Right at the top: Increasing the prices of drugs annually beyond any objective measure of increasing demand in the marketplace, or the rate of inflation generally, or within the healthcare system specifically.

While the prevalence of certain diseases may be increasing, it is impossible to argue that the industry's unrelenting pace of price increases is driven by the laws of supply and demand. Nor is it possible, in the vast majority of cases, that the same drug has somehow increased in value.

Even less admirable: Accelerating the rate of price increases in the waning years of a drug's patent life. This squeezes profits out of the system without providing value, leaves less room to pay for new innovations and results in higher prices for generics.

And one of the most cynical: Manipulating the regulatory system to increase a drug's exclusivity when its patent life is at the end. REMS, for example, should be used as they were intended — to protect patients — not to deprive them of affordable alternatives after a company has enjoyed the monopoly permitted under law.

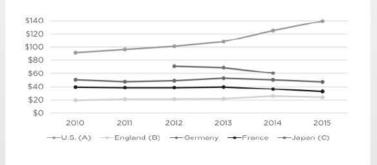
"We made a compromise to allow innovators to price at a premium to reward the substantial risk-taking in developing products," Gottlieb told BioCentury. "We are willing to accept that trade-off as a society based on the expectation that the period of exclusivity is time-limited. When it is not, it undermines the whole premise of the contract we've entered into."

The drug industry can't absolve itself by disavowing the egregious actions of outliers such as Marathon Pharmaceuticals LLC and Turing Pharmaceuticals AG. These bad apples exacerbated but did not cause the destruction of industry's reputation.

Even when companies are working on new paradigms for value, pricing and access, they can be seen to be engaging in self-serving behaviors. For instance, Novartis is a pathfinder in at least two innovative value-based pricing experiments that aim to increase access to Kymriah and heartfailure drug Entresto sacubitril/valsartan (see "Pathfinding for Access").

#### FOOTING THE BILL

National governments are among the largest purchasers of prescription pharmaceuticals, with five of the biggest developed nations spending almost \$300 billion annually from 2012 to 2014. Data below include government spending on prescription pharmaceuticals across all hospital, outpatient and other channels, except as noted. Values are nominal and have been converted to U.S. dollars using the exchange rate on the last day of the country's fiscal year. (A) Retail prescription sales only; (B) Fiscal year is from April 1 to March 31, and data for FY10, FY11 and FY15 not available; \$B; Sources: CMS, NHS Digital, Eurostat, French Health Accounts Committee, Japanese Ministry of Health, Labour and Welfare (MHLW)



At the same time, the pharma's Gleevec imatinib provides one well-studied example of the pricing policies that have turned the public and physicians against drug companies. When Gleevec was launched in 2001, its ability to turn chronic myelogenous leukemia (CML) from a death sentence into a manageable chronic disease was hailed as a breakthrough.

In an extraordinary demonstration of enthusiasm, HHS Secretary Tommy Thompson held a press conference to announce FDA's approval. There was only a little grumbling about the average worldwide price of \$26,000 per year, and \$30,000 in the U.S.

In a book about Gleevec's development, former Novartis Chairman and CEO Daniel Vasella said the launch price was intended to allow the pharma to recoup its development costs in about two years.

By the time Gleevec patents expired in the U.S., the price was over \$146,000 per year.

In a practice that is typical across the industry, and that clearly violates any commitment to patients, much of the price increase occurred in the three years prior to the U.S. patent expiration (see "Out with a Bang").

The innovator price escalation also has had the perverse effect of making the generic versions more expensive. In August 2017, more than a year after generic imatinib launched in the U.S., the cheapest generic cost about \$3,800 per month, which works out to \$45,600 per year — more than 50% higher than the branded drug's launch price.

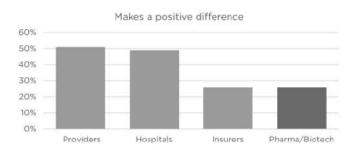
Meanwhile, Novartis continues to provide co-pay assistance that encourages patients to stick with the branded product, which costs more than twice as much as the generic, although there is no evidence that it is better than the generic.

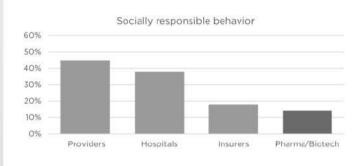
## OPINION POLL

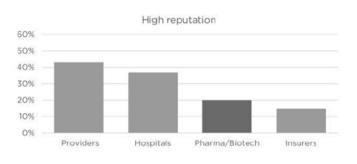
The 2016 Harris Poll Study of Reputation Equity and Risk Across the Health Care Sector asked 1,018 U.S. adults about their opinions of pharmaceutical and biotechnology companies; healthcare providers such as doctors and nurses; hospitals; and health insurers. More respondents said biopharma companies had a "high" reputation

compared with responses for insurers. But biopharma ranked last or tied with insurers for last on questions of whether each industry "puts patients over profits," "makes a positive difference in the country," and engages in "socially responsible behavior." Source: The Harris Poll









This may reduce out of pocket expenses for patients while simultaneously preserving the company's bottom line, but the tactic is objectionable in at least two ways.

First, it only shifts the financing burden to other stakeholders, in this case PBMs and plan sponsors. Society ultimately pays because the money that would have been saved by generics could have been applied to other urgent medical needs.

According to a June report from the Congressional Research Service, co-pay coupons overall are associated with both a decrease in generic substitution and with increases in the prices of branded drugs.

Second, propping up declining brands with subsidies invites attacks on other forms of patient assistance that Back to School argues are essential to assuring patients have access to important innovator drugs. These programs are necessary in the face of public and private payers' use of copays and high deductibles to ration effective treatments while pinning the blame on drug manufacturers.

Dubious price escalation isn't limited to cancer drugs.

According to the American Diabetes Association, the "cost of insulin nearly tripled between 2002 and 2013" and Americans are being forced to choose between rationing insulin and doing without other basic necessities.

"Rationing of insulin is a life-threatening practice and increases the risk of the horrific complications of diabetes including blindness, amputation, kidney failure, heart disease and stroke," the ADA noted in November 2016.

Also last year, the U.S. Centers for Disease Control and Prevention reported nearly one in five Americans aged 45-64 with diabetes reduced or delayed medication to save money.

Insulin companies say they increase list prices to compensate for rebates captured by PBMs. For example, from 2001 to 2016, the list price of a vial of Novolog insulin aspart from Novo Nordisk A/S increased 353% in the U.S., while the net price increase – the money Novo retained — was 36%, according to the pharma.

That's slightly below the cumulative rate of inflation for the period, which was 38%. But diabetes patients who have plans that tie co-pays to

list prices don't care about that excuse, and Novo has since committed to capping price increases.

Back to School acknowledges that drug companies have no control over co-pays and co-insurance, which are dictated by insurers attempting to control their own costs. But that fact does not absolve drug companies of the impact of list price increases on the patients they are supposed to serve. Rather, it highlights the imperative for drug companies to work with other healthcare stakeholders on new value-based systems of pricing and reimbursement that ensure access to medicines that work (see "Rationing by Any Other Name").

Bad choices about pricing aren't the only problem: the public and politicians are incensed by many of the drug industry's routine practices that they believe limit access and raise costs.

Individual companies continue to sully the entire industry by using legal loopholes to prolong monopolies, for instance, by abusing REMS and cutting deals to delay the introduction of generic drugs.

Even Gottlieb, hardly a card-carrying pharma-basher, has called out manufacturers of innovative drugs for stifling competition. Soon after he was sworn in, Gottlieb accused drug companies of misusing REMS and using other tactics to prevent generic and biosimilar manufacturers from obtaining drug samples, and prolonging negotiations with generic firms over the implementation of shared REMS systems to delay competition.

In July, Gottlieb told Congress that FDA is aware of more than 150 instances where a manufacturer used a REMS to block access to drug samples needed to develop a generic drug.

"Branded companies are using our rules that are intended to protect consumers, or meant to make the regulatory process more predictable, and taking advantage of these rules in order to deliberately forestall the entry of expected generic drug competition. In other words, they are 'gaming' our system," he told Congress.

Gottlieb, a former venture partner at VC firm New Enterprise Associates and formerly a fellow at the American Enterprise Institute, said generic competition reduces cost and increases access.

Gottlieb told BioCentury that FDA will try to stop abuse of REMS through regulations. He added, however, that "the bigger phenomenon" is the use of contracts with "supply chain intermediaries" to restrict the ability of generic companies to obtain the drug substance they need to develop their low-cost alternatives.

These and other drug industry tactics put the business model for innovation at risk, according to Gottlieb.

### JAPAN'S INNOVATION POTHOLE

Regulatory reforms in Japan, including the Sakigake accelerated approval pathway, are encouraging a first-in-Japan approach to developing novel therapeutics. But the threat of out-of-control spending on breakthrough medicines launched first in Japan has driven finance policymakers to instigate pricing reforms that could wash away regulatory gains.

The Ministry of Health, Labour and Welfare (MHLW) is set to implement across-the-board pricing reforms by next April 1, the start of FY18.

Japan controls drug spending via a system managed by the MHLW's Central Social Insurance Medical Council (Chuikyo), a body that imposes mandatory price reviews — and usually reductions — every two years. First-in-class drugs receive an initial price based on a combination of cost-plus and reference pricing methods. These drugs can be eligible for premiums.

Next-in-class drugs with proven benefits over a reference drug, Orphan drugs and drugs approved for some pediatric indications also can receive premiums.

In total, the premiums can add 5-120% for best-in-class drugs, and 50-100% for first-in-class drugs.

A drug can be exempted from repricing if it has been on the market for less than 15 years, no generics exist and the sponsor also has drug candidates in development "that could truly contribute to the improvement of medical care quality," according to a 2017 primer on Japanese pharmaceutical regulations compiled by the Japan Pharmaceutical Manufacturers Association (JPMA) with oversight by MHLW.

One Pharmaceutical Co. Ltd.'s Opdivo nivolumab, a breakthrough drug launched first in Japan, revealed unanticipated consequences of the regulatory innovations.

With no foreign price to use as a reference and an initial approval for an Orphan indication, Opdivo garnered a price tag almost three times that of the eventual U.S. listed price.

As the PD-1 inhibitor added large new indications, spending ballooned by more than 150% of what the Ministry of Finance expected, and Chuikyo conducted an *ad hoc* assessment that cut the mAb's price by 50%.

Now, led by concerns from the Ministry of Finance that other breakthrough drugs could threaten the government's ability to provide comprehensive healthcare for all citizens, MHLW has outlined reforms that could amount to a complete overhaul.

The proposals include annual repricing for all drugs and additional scheduled reviews for drugs that get expanded labels, along with changes to how reference price is determined.

MHLW also will implement a cost-effectiveness assessment that has been in pilot testing.

The ministry told BioCentury any drug could be subject to cost-effectiveness review, though in practice these would likely be limited to high-cost drugs. There may also be changes to the way Chuikyo determines what drugs will be given premium pricing.

# ANYONE WHO IS OR KNOWS A PATIENT WHO IS UNABLE TO OBTAIN MEDICINES HAS CONCLUDED THE DRUG INDUSTRY IS NOT HOLDING UP ITS END OF THE DEAL.

"I support a market-based model for pricing innovation," he said. "That model is predicated on a period of exclusivity granted to innovators that has a clear end."

When drug companies game the system to hinder generic competition, he added, it "diminishes people's willingness to support the market-based model of pharmaceutical innovation."

In addition to routine misbehaviors by individual companies, the industry has collectively chosen take-no-prisoners positions on public policy issues that have helped destroy the reputation of the biopharma sector, and burned up much of its political capital.

The industry's history of spectacular own-goals stretches over decades. They include opposing Nelson Mandela in a dishonorable effort to prevent South Africa from importing low-cost AIDS drugs, and a futile attempt to maintain perpetual monopolies on biologics in the U.S. by arguing that FDA violated the U.S. Constitution by even *thinking* about a biosimilar application.

More recently, industry blew off the opportunity to work with CMS to define a value-based purchasing system for Medicare Part B drugs. Instead of trying to improve a flawed plan, it defended an indefensible reimbursement system that rewards use of the most expensive medicines by pegging physician reimbursement for drugs to the average sales price (ASP).

The list goes on, including opposition to data transparency proposals in the EU and U.S., the Orphan Drugs Act and the legislation that created pediatric Priority Review vouchers (see "Own Goals").

#### MANAGEMENT INCENTIVES

Companies must publicly align management incentives with patient and public health, not just shareholder returns.

The litany of bad choices begs the question of what are good choices. One place to start is to create incentives for management and boards to choose public health over short-term shareholder yield.

The most visible place to accomplish that is in pricing, where some companies have at least started to revise the narrative.

Pricing drugs no longer can be an exercise where pharmas titrate to the highest level insurance companies and PBMs are willing to pay or a patient is willing to sacrifice.

Brent Saunders, chairman, president and CEO of Allergan plc, recognized this in a September 2016 blog post titled "Our Social Contract with Patients."

"The health care industry has had a long-standing unwritten social contract with patients, physicians, policy makers and the public at large," Saunders wrote. He said companies that have taken "aggressive or predatory price increases" have violated the contract, and made specific commitments for Allergan to honor that unwritten deal.

The element of his pledge that received the most attention was a cap on price increases in the U.S. to a single-digit percentage hike no more than once a year. Saunders said he expected the overall increases, net of rebates and discounts, would be in the low-to-mid single-digit percentages, "slightly above the current annual rate of inflation."

Saunders added that Allergan would refrain from increasing the prices of drugs nearing patent expiration unless there was a corresponding increase in the company's costs.

"While we have participated in this industry practice in the past, we will stop this practice going forward," he said.

In January 2017, Allergan announced list price increases that averaged 6.7%. The company said the price increase for every product was below 10%, that it expects the net increase across its portfolio to be 2-3% after discounts and rebates, and that it would not take any additional price increases this year.

Several companies are getting on board with the idea that wanton price increases are undermining the industry's reputation and must cease.

"The real reason we're not liked, in my opinion, is because we as an industry have used price hikes to cover up the gaps in innovation," Leonard Schleifer, CEO of Regeneron Pharmaceuticals Inc., said at the Forbes Healthcare Summit in New York in December 2016. "I hate us also when I see all this stuff."

When Pfizer's Read responded that drug costs as a percentage of healthcare spending have remained constant for the past two decades, Schleifer shot back: "You're not entitled to a fraction of the GDP."

Regeneron's marketing partner Sanofi is one of at least six companies that have joined Allergan in vowing to cap list price increases.

In May, Sanofi published its principles on drug pricing and said its "guiding principle" would be to limit total annual list price increases to the rate of medical inflation using the U.S. National Health Expenditure growth rate as its benchmark. Sanofi said the growth rate this year is projected to be 5.4%.

Johnson & Johnson did not take up Allergan's pledge, but did say it has been keeping annual list price increases in the U.S. in the single digits since 2012, with net price increases close to inflation levels.

Merck released similar data going back to 2010. And both pharmas committed to updating their price transparency reports annually.

To live up to the social contract, more companies will have to sign on, and all the companies will have to do a better job of keeping their commitments than the last time such pledges were made.

In 1990, when Vagelos pledged to keep Merck's drug price increases at or below the rate of inflation, the rest of the industry responded to his implied challenge with deafening silence — until the threat of price controls started to look real.

In March 1993, after the Clinton administration began advocating explicit drug price controls as part of its healthcare reform plan, PhRMA (then called the Pharmaceutical Manufacturers of America) asked the U.S. Department of Justice for an exemption from antitrust laws that would allow it to enforce a voluntary pledge by member companies to cap price increases at the level of inflation.

At the time, nine of the trade group's members had made pledges similar to Merck's; by year end another dozen companies had joined.

The antitrust waiver was denied, but a 2006 study by RAND Corp. researchers found that most companies honored the pledge, at least until the Clinton healthcare plan collapsed.

In 2004, Vagelos warned pharmaceutical companies that their pricing was putting their futures at risk. "High prices for drugs without profound medical value are turning people against the industry," he said in remarks to the Wharton School at the University of Pennsylvania.

When companies are under strong pricing pressure, the only way to sustain and build the top line is to bring more new products to market, according to Jeremy Levin, chairman and CEO of OvidTherapeutics Inc. He argues that biopharma executive compensation needs to be tied to the creation of breakthrough products that advance healthcare.

In a guest article in BioCentury in September 2016, he noted that senior management is often compensated based on EPS and total shareholder return. That creates incentives for actions that conflict with the social contract.

"We need to create compensation tools to reward successful pipeline investment, not just top-line growth and short-term stock appreciation," he wrote.

#### **FOLLOW THE MONEY**

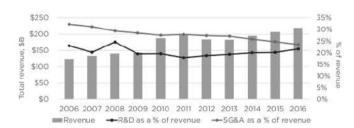
Industry's argument that high drug prices are required to help recoup R&D investments has never looked flimsier. From 2006 to 2016, sales at the 11 pure-play pharmas and biotechs in the Standard & Poor's 500 index increased at a compound annual growth rate (CAGR) of 5.8%, reaching \$219 billion last year. Much of this top-line growth has been derived from helty annual price increases on existing drugs, and the introduction of new specialty products with eye-watering price tags.

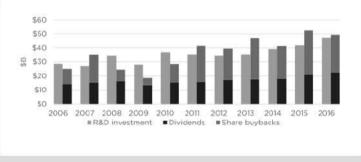
Growth in A20 has been held well below revenue growth at 2.6% CAGR, and SG&A as a percentage of revenue has dropped nearly 870 basis points to just 23.6% (top chart).

As companies have maintained sales growth while expanding margins, the added profit has not been recycled into greatly expanded R&D. Spending on R&D has grown at a 5.2% CAGR since 2006 to reach \$47.4 billion last year. As a percentage of total sales, R&D has consistently hovered in the 20% range.

Shareholders are the primary beneficiaries of this dynamic. Dividends have increased at a 4.8% CAGR since 2006 — roughly in line with sales and R&D growth — hitting \$22.6 billion last year. On the other hand, buybacks have accelerated robustly — climbing at a 9.4% CAGR since 2006 to reach \$26.8 billion in 2016 (bottom chart).

The combined value of dividends and buybacks has outpaced R&D investment over the past decade at \$403 billion to \$389 billion. Since 2011, the combined dollar amount of dividends and buybacks has been larger than R&D expenditures each year. Analysis includes acquired in-process R&D (IPR&D) expenses. Source: BCIQ: BioCentury Online Intelligence, SEC fillings, company reports





Because executives inherit the investments of their predecessors, these tools would include both incentives and "clawbacks" to reward or penalize past decisions, he wrote.

Levin is a member of BIO's executive committee. His experience includes serving as president and CEO of Teva Pharmaceutical Industries Ltd. and as SVP for strategy, alliances and transactions at Bristol-Myers Squibb Co.

Any executive compensation scheme should give CEOs freedom to maintain robust investments in R&D and encourage them to find other ways to maintain or even increase profit margins.

Beyond the obvious negative effects on pipelines, flattening R&D investment invites government intervention.

During the 2016 U.S. presidential campaign, Hillary Clinton proposed to "require pharmaceutical companies that benefit from federal support to invest a sufficient amount of their revenue in R&D." Companies that failed to do so should be required to increase investment, or pay rebates to support basic research, she said.

U.S. politicians today are questioning the industry's commitment to research, accusing it of free-riding on NIH-funded science and proposing standards for minimum corporate R&D investments.

This thinking leads straight to the sort of demands for transparency that harm innovators without benefiting patients at all, such as the demands to disclose product-level R&D expenses written into several U.S. state drug pricing bills.

No company should be compelled to reveal product-level R&D. But Back to School argues that drug company CEOs can use transparency to improve the efficiency of R&D, providing more headroom for margins as prices continue to be squeezed.

As Back to School discussed last year, many of the bottlenecks slowing development could be eased by the precompetitive sharing of data. The development of biomarkers is one place where this almost certainly is true.

Data transparency also would reduce the replication of futility as companies fail to learn from each other and expensively repeat mistakes or end up in dead ends that could have been avoided had information been shared.

J&J has already moved in this direction. It is providing third-party researchers with access to full clinical study reports and de-identified patient-level data from all trials conducted of drugs approved in the U.S. and Europe, trials of drugs that were terminated and trials that have been accepted for publication.

CEOs also should use transparency to mute accusations of secrecy, which feed society's mistrust.

Supporting public release of FDA complete response letters would be a good place to start. CRLs typically include FDA's explanation for why a marketing application can't be approved and a description of what a sponsor would need to do to gain approval in the future.

Gottlieb told BioCentury in June that he favors redacting the letters and making them public. "There might be other products on the market or other products in development that are affected by the agency's judgment," he said.

Routine publication of CRLs and other documents would allow the scientific and medical communities to assess the reasonableness of the agency's actions.

And the experience in Europe suggests that doing so would have no adverse effects. EMA routinely notifies the public about negative opinions and refusals of marketing authorization applications for human medicinal products. It publishes Q&As describing the grounds for a negative opinion, and publishes redacted versions of refusal assessment reports.

#### **OUT WITH A BANG**

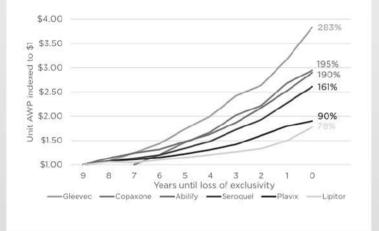
BioCentury analyzed six brands that achieved over \$4 billion in worldwide peak sales. The average wholesale price (AWP) cumulatively increased an average of 166.1% over the 10 years prior to U.S. patent expiry. Within the final three years of market exclusivity, AWPs increases averaged 33.1%.

Gleevec imatinib mesylate from **Novartis AG** (NYSE:NVS; SIX:NOVN) led the group on both metrics, increasing 283.1% in aggregate over the 10 years before its patents expired and 45.2% within the last three years.

Two brands have seen routine price increases following genericization. The AWP for Lipitor atorvastatin from **Pfizer Inc.** (NYSE:PFE) has increased an average of 8.1% annually since 2011, translating to a 155.5% cumulative increase following patent expiry. Similarly, the once-daily formulation of Copaxone glatiramer acetate from **Teva Pharmaceutical Industries Ltd.** (NYSE:TEVA; Tel Aviv:TEVA) has increased 7.9% each year since patent expiry in 2015.

Abilify aripiprazole is marketed by **Bristol-Myers Squibb Co.** (NYSE:BMY) and **Otsuka Pharmaceutical Co. Ltd.**; Seroquel quetiapine by **AstraZeneca plc** (LSE:AZN; NYSE:AZN); and Plavix clopidogrel by **Sanofi** (Euronext:SAN; NYSE:SNY) and BMS.

AWPs are indexed to \$1 per unit. AWPs are fixed at a 20% premium to wholesale acquisition cost (WAC); increases in AWP thus reflect list price increases by the manufacturer. Source: BCIQ: BioCentury Online Intelligence, Red Book, company reports



#### ACCESS, ACCESS, ACCESS

 $Most importantly, drug \, companies \, must \, be \, seen \, to \, be \, improving \, access \, to \, medicines.$ 

Voluntary commitments to cap price increases are a show of good faith, but they do not solve access problems.

Back to School can't provide a definitive list of concrete actions that will result in more access, because it's a shared problem that will require collaboration among several industries and government. But the starting points for the drug industry are clear.

Improving access begins with reducing prices of some drugs, eschewing premium pricing for new drugs that provide only incremental improvements over standard of care, and eliminating price increases that are not justified by improvements in value to patients and health systems.

It includes refraining from abusing IP protections or exploiting loopholes to prevent cheaper generics and biosimilars from coming to market at the appropriate time.

Crucially, the winning formula includes working with other healthcare sectors to help solve systemic access problems — even those that biopharma companies have not created — including facilitating a shift to a transparent reimbursement system that fully rewards interventions that improve outcomes.

As Back to School has been arguing since 2013, the prices of newly launched drugs will have to be supported by objective assessments of value that justify reimbursement and thus ensure access.

"Access to medicines is only available when you truly demonstrate benefit. More holistic assessment will inform payers and patients, who increasingly contribute more, to care about the value that's being delivered to them," John Glasspool, an advisor to the New Drug Development ParadIGmS (NEWDIGS) program, told BioCentury.

NEWDIGS is housed within the Massachusetts Institute of Technology's Center for Biomedical Innovation (CBI). The group laid the groundwork for EMA's adaptive licensing pathway. Its current projects include work to design and pilot financing and reimbursement models for curative therapies, and to demonstrate how data obtained outside of randomized clinical trials could be used to develop meaningful outcomes measures and support regulatory and access decisions. Its collaborators include academics, regulators, drug companies, patients and payers.

Glasspool was previously EVP and head of corporate strategy and customer operations at Baxalta Inc., which was acquired by Shire plc.

"There is a sense of urgency, mixed with frank awe" for the quality of innovation payers, providers and patients are seeing, noted Steven Pearson, founder and president of the Institute for Clinical and Economic Review (ICER). "Cures for hepatitis C and new CART drugs are the kind of innovation everyone welcomes. Yet they are worried because they don't see how paying for these fits in with the other things they need to pay for."

ICER is a non-profit organization that evaluates evidence on the value of medical interventions. It publishes suggested "value-based price benchmarks" that payers use in negotiating prices of drugs and devices.

"Drug companies have a responsibility to make defining value a collaborative process," Pearson told BioCentury. "That doesn't mean they need to accept someone else's definition of value, but they do have to engage with other stakeholders."

Pearson says there are signs that drug companies recognize the need for value-based pricing, and predicted they will find solutions that don't involve price controls. However, he warned, "If pharmaceutical manufacturers continue to have this much power over prices and society feels it is being abused, the system will be changed and European models imposed."

While Saunders did not explain how, he explicitly committed Allergan to pricing "products in a way that is commensurate with, or lower than, the value they create by mitigating or avoiding the need for other treatment modalities or providing better quality of life to those patients without other treatment options."

# RATIONING BY ANY OTHER NAME

The drug co-pay issue demonstrates the urgent need for value-based metrics to determine healthcare spending.

Drug companies are routinely scored as the villain when patients complain they cannot afford co-pays or deductibles that result in high out-of-pocket payments for their medicines.

While escalating list prices of drugs are the trigger, drug companies have not imposed the out-of-pocket burden. Insurers have designed plans to control how much they spend on drugs.

Co-pays are mandated by law in the case of Medicare Part B, or by business decisions in the case of private payers.

In either case, the co-pay is not correlated with any objective calculation of value.

Even worse, co-pays are structured to prompt use of drugs that are more profitable for PBMs than alternative treatments, or to increase PBM profits by shifting the cost of expensive therapies to the individual patient.

PBMs and payers also cannot be relied upon to pass the savings from rebates and discounts to patients. As a result, co-pays can exceed the net cost of a drug. For example, a survey of its members by the National Community Pharmacists Association (NCPA) in June 2016 revealed that patients were charged co-pays that exceeded a PBM's costs for a generic allergy spray and a generic cholesterol drug.

While payers can point to a drug's list price to deflect blame to the pharma company, a high co-pay has pernicious effects on access — patients make decisions to forgo or scrimp medicines based on affordability.

As opinion polls show, the public is not stupid. It puts insurers down in the cellar with drug companies. But Back to School notes the drug industry has brought retribution down on itself by practices such as boosting the prices of old drugs. As a consequence, society only can see eye-popping prices for novel medicines that in many cases could be justified by the remarkable outcomes they produce.

This is why drug companies, their executives and boards must commit themselves to a business model that correlates payments to the actual outcomes created for the patient. It is the ultimate objective for an industry that desperately needs to rehabilitate its contract with society.

Sanofi said it would consult with "external stakeholders" and would base its launch prices on a "holistic" assessment of value, including clinical outcomes, economic value and social value. It defined the latter as improvements in quality of life and productivity.

The pharma said its pricing process for new medicines also would take into account similar treatment options that are or will soon be available; affordability for patients, payers and healthcare systems; and factors such as the need to fulfill regulatory commitments, conduct additional trials and develop sophisticated patient support tools.

While such approaches may dovetail with the health technology assessment (HTA) model that drives many single-payer systems, the drug industry is falling behind in the U.S., which is the major reservoir of global profits, as the healthcare payment system moves to replace the fee-for-service model.

Former CMS and FDA chief Mark McClellan, now director of the Robert J. Margolis Center for Health Policy at Duke University, told BioCentury drug companies aren't doing nearly enough to move to value-based pricing, and said there is not enough transparency.

### "THE FACT IS THAT TOO MANY PEOPLE CAN'T AFFORD THE MEDICINES THAT THEY NEED."

SCOTT GOTTLIEB, FDA

The American healthcare system is "going to episode payment models, new primary care payment models, and full capitation population risk models," McClellan noted. "Drug and biologics manufacturers are not closely aligned with providers that are trying to make progress in that direction."

PBMs and private payers in the U.S. including Aetna Inc., Cigna Corp., Prime Therapeutics LLC, and Harvard Pilgrim Health Care Inc. have been experimenting with outcomes-based contracting.

Express Scripts Holding Co. and CVS Health Corp. are testing indication-based payment models for drugs approved to treat more than one indication

Harvard Pilgrim has tried to engage drug sponsors in a pilot of episode-based payment that would reimburse a flat amount for an episode of care, regardless of the amount of drug used. CMO Michael Sherman said he hasn't gotten any uptake on that model. However, he added manufacturers are showing "more interest in the outcomes-based approach."

Payers and PBMs have told BioCentury that biopharma companies could be subject to fewer restrictions and see a net increase in use of their drugs — meaning more access for patients — if they joined in testing these new models.

Sadly, the number of biopharma companies that have disclosed their participation in value-based pricing deals remains insignificant. And last

year, when the industry had a chance to test these models on a large scale within the Medicare Part B drug benefit, it not only balked, it went on the attack to kill the proposal.

McClellan acknowledged there are obstacles to value-based pricing in the U.S. that could be alleviated through legislation and regulation, but he argued these have been exaggerated. "There are ways to manage many of those perceived impediments," he said.

McClellan served as CMS administrator and FDA commissioner in the George W. Bush administration, and currently serves on the board of J&J.

Novartis appears to have found a way around obstacles to valuebased pricing for Kymriah via an outcomes-based deal with CMS. In its approved indication for children and young adults with acute lymphoblastic leukemia (ALL), the pharma will receive payment only for patients who respond to Kymriah by the end of the first month.

The arrangement also includes indication-based pricing, under which the terms of payment for future indications "would be reviewed for the most relevant outcomes-based approach."

McClellan also told BioCentury reducing systemwide costs will require "better evidence about what we are getting for what we are spending. More transparency on outcomes and cost information on what matters to patients and payers would really help."

To that end, drug companies should work with patients to produce data on outcomes — including data that aren't typically included on FDA labels — that help them optimize their care. They also should collaborate with payers to generate information that would allow patients to assess the cost and performance of alternatives.

Back to School reiterates that a lack of transparency on prices invites suspicion and leads to false assumptions about the relationship between drug prices and company cost of goods and investment in R&D. But it is the industry's own arguments that have led to this predicament. The constant drumbeat that high drug prices are needed to recoup R&D investments has fueled demands to disclose detailed costs associated with the development and manufacturing of specific drugs.

An early example came from the U.K. in 2014, when NICE tried to demand R&D costs to negotiate the price of Orphan drug Soliris eculizumab from Alexion Pharmaceuticals Inc. The agency said it was unable to make a recommendation on the drug because the appraisal committee could not justify its cost "in light of the manufacturing, research and development costs of a medicinal product for the treatment of a very rare condition."

NICE did not succeed in extracting the R&D numbers from Alexion, and Soliris was eventually recommended with restrictions, but the idea that R&D cost could be used to determine value did not die there.

In the U.S., pharmaceutical cost transparency laws making their way through state legislatures are seeking to pave the way for drug price controls by exposing profit margins on high-priced drugs.

Other aspects of access are not within drug company control, and other healthcare players must be called out for practices that let patients and society down.

For example, if transparency is demanded of drug companies, what about the unfathomable prices charged by hospitals?

### **OWN GOALS**

The pharmaceutical industry has a long history of alienating patients and potential allies by aggressively pursuing self-destructive public policies. For example, in the late 1990s, after three years, an unknown number of unnecessary deaths, countless ugly headlines and an outpouring of activism had darkened its reputation, the pharma industry admitted that South African imports of cheap AIDS drugs were legal under international trade law and dropped litigation that sought to stop it.

In a more recent example, industry negotiated with Congress to create an **FDA** biosimilars pathway only after it became clear that killing biosimilars outright was not possible. Industry's opposition caused the U.S. to cede commercial and regulatory preeminence to Europe, and squandered an opportunity to foster competition that could have blunted the demand for price controls.

Even laws that are now celebrated by drug companies — like the Orphan Drug Act — were passed over the objections of pharma companies. "The pharma industry made the same mistake on the Orphan Drug Act that it did on any legislation introduced by Henry Waxman," Abbey Meyers, the founder of the **National Organization for Rare Disorders** (NORD), told BioCentury. "If Waxman proposed it, the industry's knee-jerk reaction was to oppose it, and believe me they pulled out all weapons to stop the ODA from being enacted."

In many cases industry has reversed its position, embracing laws or regulations it tried to kill. According to Nancy Goodman, **PhRMA** lobbied against the Creating Hope Act. The bill has since led to biopharmaceutical companies trading more than \$1 billion in Priority Review vouchers for rare pediatric diseases. Goodman, the founder of **Kids v Cancer**, conceived of and led efforts to enact the bill.

Industry continues to oppose policies that are sure to be implemented and unlikely to produce any harm, such as proposals by **EMA** and FDA to release de-identified patient-level data from clinical trials. The **European Federation of Pharmaceutical Industries and Associations** (EFPIA) and PhRMA want, and EMA has rejected, a gatekeeper to evaluate third-party researchers' analysis plans before granting access to data. Seeking to circumvent EMA's and FDA's proposals, PhRMA and EFPIA have adopted principles on data sharing that give companies discretion to deny requests that would help competitors.

Selected examples of industry's policy black eyes are below.

| Policy/law                                                               | Country/<br>region | Key provisions                                                                                                                                                        | Industry position                                                                                                                                                                                                                                                                                                                                                                                                                         | Outcome                                                                                                                                                                                                               |
|--------------------------------------------------------------------------|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Biologics Price Competition<br>and Innovation Act (BPCIA)                | U.S.               | Created pathways for both biosimilars and interchangeable biologics                                                                                                   | BIO: There is no way to determine the active ingredients of a biologic or use analytic methods to determine similarity BIO: Referencing another company's data — even after patent expiry — constitutes "use of others' work without just compensation" PhRMA: Approving biosimilars would constitute unconstitutional property confiscation BIO, PhRMA, several biologics manufacturers: Interchangeability is scientifically impossible | Congress passed BPCIA in 2009, creating a pathway for biosimilars and interchangeable biologics. The first biosimilar wasn't approved in the U.S. until 2015, nine years after biosimilars were introduced in Europe. |
| Clinical Trial Regulation No.<br>536/2014                                | EU                 | Release de-identified patient-level<br>data from clinical trials                                                                                                      | EFPIA, PhRMA: Unvetted third-party analyses<br>could cast doubt upon regulatory decisions                                                                                                                                                                                                                                                                                                                                                 | EMA policy on transparency<br>went into effect in 2014 but<br>implementation has been delayed<br>until 2019 pending creation of IT<br>systems; a similar proposal by FDA<br>has stalled                               |
| Creating Hope Act                                                        | U.S.               | Provides Priority Review vouchers for rare pediatric drugs                                                                                                            | PhRMA: Lobbied against the bill in 2012, then<br>strongly supported its reauthorization in 2016                                                                                                                                                                                                                                                                                                                                           | Enacted in 2012 as part of the<br>FDA Modernization Act, and<br>reauthorized in 2016                                                                                                                                  |
| HHS rule on data transparency                                            | U.S.               | Requires inclusion of summary<br>results on ClinicalTrials.gov for all<br>studies of products in Phase II and up,<br>regardless of product approval status            | BIO: Disclosure would not add value to the<br>website and would divert resources from drug<br>R&D                                                                                                                                                                                                                                                                                                                                         | Proposed in 2014, implemented<br>January 2017                                                                                                                                                                         |
| Medicare Part B value-<br>based drug purchasing<br>demonstration project | U.S.               | Attempted to replace Part B reimbursement formula, which uses an add-on payment based on a percentage of average sales price (ASP), with a value-based payment system | PhRMA and BIO: The proposal would limit access,<br>stifle innovation, and value-based pricing should<br>be worked out in the private sector. The trade<br>groups collaborated with physician groups to<br>demand the proposal's complete withdrawal.                                                                                                                                                                                      | Following intense bipartisan<br>opposition, CMS withdrew a<br>proposed rule that would have<br>created the demonstration project                                                                                      |
| Medicines and Related<br>Substances Control<br>Amendment Act No. 90      | South Africa       | Compulsory licenses on AIDS drugs                                                                                                                                     | PhRMA: Lobbied White House to impose trade<br>sanctions to force South Africa to abandon<br>practices that could erode IP protection for drugs     PhRMA: Sued the South African government to                                                                                                                                                                                                                                            | PhRMA dropped the litigation after<br>three years                                                                                                                                                                     |
| Orphan Drug Act                                                          | U.S.               | Creates incentives for development of drugs to treat rare diseases                                                                                                    | prevent it from importing low-cost AIDS drugs                                                                                                                                                                                                                                                                                                                                                                                             | Enacted in 1983, followed by similar<br>legislation in Japan and the EU                                                                                                                                               |

The PBM situation is particularly perverse as its business model is built on extracting rebates that do not necessarily contribute to lower payer or patient costs. In fact, the PBM model encourages drug companies to jack up list prices in anticipation of the demand for rebates.

This is one instance where drug industry management and boards owe it to their shareholders to hold a spotlight on profiteering.

However, a war on PBMs will not help patients unless both sides stop protecting their short-term P&Ls at all costs and begin to collaborate on solutions that address the social contract.

"I don't believe that pointing fingers, blaming one industry, is at all constructive," Ovid's Levin told BioCentury. "For a long time several components of the system have been quite comfortable having the pharmaceutical and biotech industry take the blame for price rises. We all — PBMs, distributors, insurers and pharmaceutical companies — have a common responsibility to ensuring we bring affordable access to great medicines," he said.

Novo has explicitly committed to collaborating with payers, PBMs, insurers, employers and patient organizations to simplify and improve the complex pricing system in a position paper about pricing and affordability posted on its website.

Saunders also vowed to expand Allergan's patient assistance programs, to engage in responsible education about its products and to maintain quality and ensure availability of the pharma's products. Other pharmas have made similar pledges.

Patient assistance programs that provide free drugs to patients who lack insurance coverage, or pick up some or all of the costs for deductibles and co-pays for eligible patients, are among the most powerful tools for drug companies to improve access.

However, according to Marc Boutin, they need to be more consistent, stable and easier to access.

Boutin is CEO of the National Health Council (NHC), an umbrella group representing patients with chronic diseases and disabilities. Its members include patient advocacy organizations, as well as biopharma companies and payers.

Drug assistance programs "are an incredible challenge for patients," Boutin told BioCentury. "Programs differ from company to company, product to product. The rules on how they operate can change on an annual or quarterly basis. You need to know how to find them, which is difficult for the ordinary patient."

# PRICING DRUGS NO LONGER CAN BE AN EXERCISE WHERE PHARMAS TITRATE TO THE HIGHEST LEVEL INSURANCE COMPANIES AND PBMS ARE WILLING TO PAY OR A PATIENT IS WILLING TO SACRIFICE.

"The system we currently have is very complicated — rebates, discounts, administrative fees, co-pays and deductibles all play a role in what our customers, and people with diabetes, pay. We need to work with all involved to simplify and transform the system," the pharma wrote.

McClellan noted the system needs to change, because there is no reason to think prices would come down under the current paradigm without the negotiating leverage of PBMs.

"If you don't like this non-transparent system for having very large purchasers negotiate to get prices down, what's the alternative?" McClellan said. "One is to switch to a system based on value and the results patients are getting as an alternative to price negotiation."

Consensus on a product's value is critical for establishing a price, but it is not sufficient. For patients, value-based pricing still will be indistinguishable from extortion when a drug's high price isn't accompanied by guarantees about access.

In his pledge, Saunders committed Allergan to working with government payers, regulators, private insurers, and PBMs to make the company's products accessible.

He added: "At the same time, millions of American patients get access through these programs."

A June report from the Congressional Research Service noted that according to tax records, total giving by patient assistance programs run by 10 large biopharma companies rose from \$376 million in 2001 to \$6.1 billion in 2014. Independent patient assistance charities increased their giving over the same period from \$2 million to \$868 million.

There is a clear need for more creativity around means-tested access. The bottom line is that no patient should be denied treatment because they can't pay, and no one should be forced to sell their home or bankrupt their family to qualify for assistance.

The "Help at Hand" program from Takeda Pharmaceutical Co. Ltd.'s U.S. business provides an example to follow. Help at Hand provides 11 marketed drugs at no or reduced cost to Americans with incomes up to 400% of the Federal Poverty Level. For a family of four, the cutoff is \$100,000 in annual income.

The application is simple and easy to find. It asks for insurance information, and for documentation of annual income. It does not ask about savings or other assets.

As of April 2016, Help at Hand had provided more than 1 million prescriptions to over 200,000 patients in the U.S. The company operates a separate assistance program for oncology products.

Takeda includes contact information for its assistance program on drug ads.

Just as it is unacceptable to deny access to life-saving drugs to lowincome patients in wealthy countries, the social contract means it is not acceptable for patients in low-income countries to suffer and die because they cannot afford drugs.

Some companies also have implemented generous programs for ensuring access to medicines in poor countries, but drug manufacturers can't solve problems of global access on their own. To fulfill the contract, more drug companies must do more to collaborate with governments, NGOs and industry in developing countries.

Companies also must improve access to unapproved drugs.

There may be legitimate reasons, including supply constraints, for restricting or denying pre-approval access, but manufacturers of breakthrough products have an obligation to attempt to overcome those constraints. When they can't be overcome, companies must provide timely explanations to patients.

Failures to do so have reinforced public perceptions of biopharmaceutical companies as heartless profit-seekers and provided ammunition to ideologues with an antiregulatory agenda.

The right-to-try battle in the U.S. is based on the false premise that FDA is the principal roadblock to patients accessing unapproved therapies. In fact, access is almost entirely determined by companies that own the drugs.

Opponents and skeptics believe right-to-try legislation would harm patients by exposing them to untested therapies and delaying the collection of data that are essential for approvals. Transparent compassionate access policies, and large-scale expanded access programs, are the antidotes.

J&J provides one model. The pharma implemented a comprehensive preapproval access policy that includes an independent advisory board that evaluates requests for compassionate use.

#### **ACTION ITEMS**

Even if the drug industry individually and collectively reforms itself, Back to School acknowledges it will take time to repair biopharma's reputation.

The current reality is that the drug industry gets little or no recognition even when it scrambles to develop medical countermeasures to urgent public health threats.

One example is the industry's extraordinary response to the Ebola epidemic. Several biopharma companies with unique capabilities put high-priority R&D on hold, diverted scientists from product development, collaborated transparently with governments and NGOs, and developed prototype vaccines in record time.

If something as stark as working to stop an epidemic in its tracks doesn't capture the public's imagination, it is unlikely that any changes in biopharma's more routine business will spark a quick turnaround in its reputation.

As noted at the beginning of this essay, the marriage between the drug industry and its customers has been unwinding for decades. It will take a long time to restore that trust.

Rehabilitation will take actions, not words in press releases. Beyond the strategic approaches described above, like using transparency to mute accusations of secrecy, Back to School advocates this starter list of five action items for drug companies:

Actively and visibly demonstrate industry's devotion to collaborating on valuebased metrics for pricing and reimbursement.

Some work has begun here, such as Novartis' deals with payers for Entresto. The pharma shares the risk by paying rebates based on whether hospitalizations exceed or drop below an undisclosed threshold. Hospitalization is a good metric for plans or payers that provide both pharmacy and medical benefits, because it hits their bottom line and is a proxy for health outcomes.

### "MORE TRANSPARENCY ON OUTCOMES AND COST INFORMATION ON WHAT MATTERS TO PATIENTS AND PAYERS WOULD REALLY HELP."

MARK MCCLELLAN, DUKE UNIVERSITY

However, if a value-based system is to replace the current volume-based or fee-for-service approach — as Back to School argues it must — then companies will need to work with patients and payers on a much bigger scale to devise metrics for all diseases, or at least those responsible for the lion's share of drug spend.

Support independent efforts to assess value.

Given that the public does not trust drug developers or insurers, third parties logically will need to serve as credible arbiters of value. In Europe and other parts of the world, health technology assessment bodies fill this role. In the U.S., ICER is hoping to do so.

Regeneron's collaboration with ICER on its assessment of Dupixent dupilumab for atopic dermatitis is a step in the right direction. The biotech provided data to ICER, and in return received early access to the report's conclusions for use in discussions with payers, according to Pearson.

Regeneron said ICER's report factored into Dupixent's \$37,000 list price and average net price in the low \$30,000s — well below the most commonly cited comparators but still not "cheap" by consumer standards.

Express Scripts praised Regeneron and partner Sanofi's approach to the launch as "responsible" and included Dupixent on its National Preferred Formulary.

The entire healthcare system, including drug companies, must do a far better job of generating data that can be used to make such assessments.

Biopharma companies have an "obligation to generate the best information about value that they can produce within the constraints FDA and the competitive landscape give them," Pearson told BioCentury.

Drug developers can support this work by developing data on outcomes, including quality of life, that are important to patients and payers. Partnerships with healthcare providers whose business models now require them to demonstrate improvements in the quality of care they deliver are an appropriate vehicle for generating these data.

Integrated health systems and accountable care organizations (ACOs) top the list, along with Medicare Advantage providers, hospitals and large physician groups.

Collaborate with patient groups to create and stress-test access programs.

Access programs developed by companies in a vacuum are not sufficient; patient perspectives are essential for designing access programs and assessing their effectiveness.

Rare diseases provide the most abundant examples of effective approaches, in which most if not all companies work directly with patient groups, and even individual patients, to ensure access to drugs.

Manufacturers also provide funding to assistance programs run by patient groups, like the National Organization for Rare Disorders' RareCare program. NORD uses the money to help patients with rare conditions obtain medicines; pay insurance premiums and co-pays; and obtain assistance with diagnostic testing, travel for clinical trials or consultation with disease specialists. NORD does the screening of patients for eligibility and disburses the money.

These models could be extended to more disease areas via collaboration with other patient advocacy and disease foundations.

Call détente with PBMs, insurers, governments, and providers that are willing to collaborate on patient access, while publicly calling out stakeholders that are unwilling to share responsibility for solutions.

Express Scripts, for example, has been willing to engage with drug manufacturers to design an indication-based pricing pilot in cancer. In 2015, the PBM told BioCentury it planned to work with manufacturers to discuss what drugs and indications are best suited to the pilot and to negotiate how reimbursement rates would be set for each indication.

As of December 2016, the PBM said the pilot included undisclosed drugs for four malignancies: multiple myeloma (MM), non-small cell lung cancer (NSCLC), prostate cancer and renal cell carcinoma (RCC). Express Scripts did not provide an update in time for publication.

Express Scripts also spearheaded a partnership with pharmas and pharmacies to provide discounted medicines to patients who are uninsured or have high out-of-pocket costs for branded drugs. The program provides an average discount of 34% on more than 40 branded drugs for common illnesses including diabetes, asthma, heart disease, depression, gastrointestinal disorders and gout.

Participating pharmaceutical companies include Boehringer Ingelheim GmbH, Eli Lilly and Co., H. Lundbeck A/S, Novo Nordisk, Sanofi, Takeda and Teva.

Finally, continue to create breakthrough medicines with patients as partners.

Restoring the trajectory of R&D budgets is a starting point. But to communicate its commitment to the social contract, the drug industry

should do more to embed patients in the process beyond asking them to take risks in clinical trials.

Except for Orphan drugs, biopharma is one of the few successful modern industries that fails to systematically and rapidly incorporate feedback from customers to improve the way its products are delivered, developed and distributed.

As BioCentury has pointed out in previous Back to School essays, investing in patient preference research and including patient perspectives all along the drug life cycle would result in better products with more useful data, while eliminating investment in drugs patients do not want and will not use.

Executing on this beginning list of action items — and identifying new ones — would start to repair the biopharma industry's relationship with society. And if more companies partner with patients and payers to prioritize clinical needs, define and demonstrate value, and agree on plans that ensure access to medicines, then these constituents will have a stake in protecting the industry that produces them.

At the end of the day, macroeconomics matter. In the absence of a transformational change in the drug industry's cost structure, society's limited ability to pay for drugs means that extraordinary profits will be forced down to merely above average. It's not a matter of whether this happens, but when.

The bottom line is that continuing to prioritize for short-term shareholder interests will just hasten the day when societal mandates undermine the drug industry's ability to generate sustainable returns for its investors.

Investors who demand outrageous returns will end up looking elsewhere, and there's nothing the drug industry can do about that.

If the drug industry lives up to the social contract, then in return, society will find a way to reward true innovations. That's the deal.

The 25th Back to School Commentary is a collaborative work co-written this year by Washington Editor Steve Usdin, BioCentury Editor Susan Schaeffer and President & CEO David Flores. New reporting was contributed by Steve Usdin and Senior Editor Erin McCallister. Data were developed by Amran Gowani and Meredith Durkin Wolfe, Senior Editor and Associate Editor of Research & Analytics, respectively.

#### COMPANIES AND INSTITUTIONS MENTIONED

Aetna Inc. (NYSE:AET), Hartford, Conn.

Alexion Pharmaceuticals Inc. (NASDAQ:ALXN), New Haven, Conn.

Allergan plc (NYSE:AGN), Dublin, Ireland

American Diabetes Association (ADA), Arlington, Va.

American Enterprise Institute, Washington, D.C.

Biotechnology Innovation Organization (BIO), Washington, D.C.

Boehringer Ingelheim GmbH, Ingelheim, Germany

Bristol-Myers Squibb Co. (NYSE:BMY), New York, N.Y.

Cigna Corp. (NYSE:CI), Bloomfield, Conn.

Congressional Research Service, Washington, D.C.

CVS Health Corp. (NYSE:CVS), Woonsocket, R.I.

Duke University, Durham, N.C.

Eli Lilly and Co. (NYSE:LLY), Indianapolis, Ind.

European Medicines Agency (EMA), London, U.K.

Express Scripts Holding Co. (NASDAQ:ESRX), St. Louis, Mo.

FINANCE

### BioCentury<sup>\*</sup>

Harris Poll, Rochester, N.Y.

Harvard Pilgrim Health Care Inc., Boston, Mass.

H. Lundbeck A/S (CSE:LUN), Copenhagen, Denmark

Institute for Clinical and Economic Review (ICER), Boston, Mass.

Japan Pharmaceutical Manufacturers Association (JPMA), Tokyo, Japan

Johnson & Johnson (NYSE:JNJ), New Brunswick, N.J.

Kaiser Family Foundation, Menlo Park. Calif.

Marathon Pharmaceuticals LLC, Northbrook, III.

Massachusetts Institute of Technology, Cambridge, Mass.

Merck & Co. Inc. (NYSE:MRK), Kenilworth, N.J.

Ministry of Health, Labour and Welfare (MHLW), Tokyo, Japan

National Community Pharmacists Association (NCPA), Alexandria, Va.

National Health Council (NHC), Washington, D.C.

National Institute for Health and Care Excellence (NICE), London, U.K.

National Institutes of Health (NIH), Bethesda, Md.

National Organization for Rare Disorders (NORD), Danbury, Conn.

Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland

Novo Nordisk A/S (CSE:NOVOB: NYSE:NVO), Bagsvaerd, Denmark

Ono Pharmaceutical Co. Ltd. (Tokyo:4528), Osaka, Japa

Ovid Therapeutics Inc. (NASDAQ:OVID), New York, N.Y.

Pfizer Inc. (NYSE:PFE), New York, N.Y.

Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C.

Prime Therapeutics LLC, Eagan, Minn,

RAND Corp., Santa Monica, Ca.

Regeneron Pharmaceuticals Inc. (NASDAQ:REGN), Tarrytown, N.Y.

Sanofi (Euronext:SAN: NYSE:SNY), Paris, France

Shire plc (LSE:SHP: NASDAQ:SHPG), Dublin, Ireland

Takeda Pharmaceutical Co. Ltd. (Tokyo:4502), Osaka, Japan

Teva Pharmaceutical Industries Ltd. (NYSE:TEVA; Tel Aviv:TEVA), Petah Tikva, Israel

Turing Pharmaceuticals AG, Baar, Switzerland

U.S. Centers for Disease Control and Prevention (CDC), Atlanta, Ga.

U.S. Centers for Medicare & Medicaid Services (CMS), Baltimore, Md.

U.S. Department of Health and Human Services (HHS), Washington, D.C.

U.S. Department of Justice (DoJ), Washington, D.C.

U.S. Food and Drug Administration (FDA), Silver Spring, Md.

The Wharton School at the University of Pennsylvania, Philadelphia, Pa.

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STRATEGY

### PATHFINDING FOR ACCESS

BY ERIN MCCALLISTER, SENIOR EDITOR

A pact with the Centers for Medicare & Medicaid Services for Novartis AG's CAR T therapy demonstrates leadership in new value-based drug pricing models.

Kymriah tisagenlecleucel-T represents a milestone for three reasons. Its approval by FDA on Aug. 30 was the first for a chimeric antigen receptor T cell therapy. It was the first therapy to show a durable response in pediatric and young adult patients with relapsed, refractory B cell acute lymphoblastic leukemia (ALL) who are out of options.

And it is the first pharmaceutical for which CMS has done a pay-forperformance deal.

The treatment's novelty and exceptional efficacy, coupled with hypothetical cost-effectiveness calculations by the UK.'s NICE and others, led analysts to expect a price tag in the neighborhood of \$500,000-\$750,000.

But Novartis set the list price for the one-time treatment at \$475,000 and said it would not collect payment for patients covered by CMS who do not have a response within the first month.

The pharma also said it will provide assistance for food, lodging and travel expenses for the patient and up to two caregivers to mitigate the impact of the company's decision to restrict initial distribution to 30-35 centers.

CEO Joe Jimenez said on an Aug. 30 media call that the CMS deal "will streamline delivery, reduce the costs for Medicaid programs and ensure timely access."

The fact that Kymriah is launching with CMS coverage suggests that's true. On average there is a six-month delay between launch and coverage under Medicare, and for prostate cancer treatment Provenge sipuleucel-T, the first autologous cell therapy approved in the U.S., it took about a year. Similar delays are seen in Medicaid.

The contract includes patients covered by Medicaid and the Children's Health Insurance Program (CHIP). Novartis didn't provide a specific breakdown of the proportion of ALL patients covered by government and commercial plans. According to CMS, about 62% of U.S. children received health benefits through Medicaid or CHIP.

Novartis expects a total of 600 patients per year, including both patients who receive benefits through Medicaid or CHIP and those who don't, would qualify for therapy.

The pharma suggested the arrangement with CMS could be expanded to include indication-based pricing should Kymriah's label be expanded. Under that model, if efficacy in new indications is not as high as in ALL, the price could be lower.

Next quarter, Novartis plans to submit an sBLA for Kymriah to treat diffuse large B cell lymphoma (DLBCL), a much larger indication, with about 10,000 patients in the U.S.

While the response rate in ALL was nearly 83%, data in DLBCL show a 59% best objective response rate (ORR).



THINKSTOCK

"The remission rates that we see in DLBCL are lower than in pediatric ALL, so if there were an indication-based pricing, it might lead to a lower price," Bill Hinshaw, EVP and head of U.S. for Novartis Oncology, said on the media call.

#### **MIXED REVIEWS**

Novartis relied on multiple cost-effectiveness models to determine Kymriah's price, including an analysis conducted by the University of York at the request of NICE.

The March 2016 analysis estimated that a hypothetical CAR T therapy would be cost-effective at a price of £356,100 (\$504,665) if used as a bridge to hematopoietic stem cell transplant, or £530,557 (\$750,738) if it provided a cure.

If the therapy were reimbursed only for patients who went into remission, the product met cost-effectiveness thresholds in the bridging scenario assuming an average remission rate of 70% at day 28, and in the curative scenario when the remission rate was 90%.

It is too early to tell whether Kymriah will produce cures, but there is some evidence that it could, at least for some patients.

In the pivotal ELIANA trial in 63 pediatric ALL patients, the ORR was 82.5%. Moreover, 75% of patients remained in remission at six months. At least one patient has remained in remission for five years.

"We've consulted with experts and we're very comfortable with the price we set," said Hinshaw. "We are pricing below standard of care, which has similar complications of morbidity and mortality."

The price of SOC allogeneic stem cell transplant is \$540,000-\$800,000.

Hinshaw added, "This is a one-time treatment with limited continuing costs compared to many of the other therapies out there now."

Kymriah's price includes the leukapheresis process used to extract patients' T cells, which are used to manufacture the treatment. According to a 2015 study in the journal *Bone Marrow Transplantation*, apheresis costs about \$4,192 per session.

At least one patient group says the price is still too high.

"We believe it is excessive. Novartis should not get credit for bringing a \$475,000 drug to market and claiming they could have charged people a lot more," said David Mitchell, president of Patients for Affordable Drugs. The group met with Novartis in August to urge the pharma to adopt a "fair" price.

J. Mario Molina, board member and former CEO of Medicaid plan administrator Molina Healthcare Inc., also thought the price was too high.

"The average cost is \$5,500 to cover a Medicaid beneficiary for one year. \$475,000 for one therapy is the equivalent of covering 86 people in a year. It's a bad trade-off any way you look at it," Molina told BioCentury.

Michael Sherman, CMO at regional payer Harvard Pilgrim Health Care Inc., would like to see Novartis extend the outcomes-based contract to commercial payers, and thinks an indication-based pricing approach would be a good way to control costs.

"That's exactly what we need to see to address access and affordability. I would welcome indication-based pricing where the price is tied to some benchmark of value," Sherman told BioCentury.

He said Harvard Pilgrim has not yet made any specific coverage decisions. In general, he thinks commercial plans will cover Kymriah because of its efficacy.

"I'm excited about the approval because it really presents a solid therapy for the 20% of patients who don't respond to available therapy. It's got some impressive results, and I think plans will look to cover it in the appropriate patients," he said.

Novartis told BioCentury it intends to work with commercial plans to establish value-based pricing arrangements for Kymriah.

#### CAPTURING CMS

Roger Longman, CEO of reimbursement consultancy Real Endpoints LLC, thinks Novartis was smart to work with CMS first.

When Novartis launched Entresto sacubitril/valsartan in July 2015, the pharma said it wanted to work with payers to establish outcomes-based contracts tied to the heart failure drug's ability to reduce hospitalizations. It took almost seven months to get deals done with commercial payers, because they didn't have enough affected patients to make the deals attractive. Most heart failure patients are covered by Medicare.

"I don't think that they understood that drug would be all about Medicare, but here, they've gone to the controlling entity, CMS," Longman said.

Dan Mendelson, president of Inovalon Holdings Inc.'s Avalere Health LLC unit, agreed: "When you have Medicaid or Medicare as a majority customer, it requires outcomes-based thinking and that's what they did here."

"This provides a real benefit to having a smooth launch. There's been a number of other products where there's been pushback from the federal government or states on launch prices," Mendelson said.

CMS has "been saying for months that they're open for business and now there's proof that they're open to novel arrangements that pay for value," he added.

In a press release announcing the Kymriah arrangement, CMS said it is working with "all stakeholders," including state officials, on how to implement innovative payment deals, which could include outcomesbased pricing.

The agency said it plans to issue guidance "to explain how pharmaceutical manufacturers can engage in innovative payment arrangements." It declined to give a timeline for the guidance.

And while Novartis declined to discuss how the deal was structured, it would be reasonable to think that it provides at least one more advantage: avoiding the Medicaid best price trigger.

Under the best price rule, companies must provide Medicaid with either a 23% discount or the lowest price offered to a commercial insurer, whichever is cheaper.

Companies have feared the rule could result in huge discounts to Medicaid if they did outcomes-based deals with commercial plans that resulted in refunds or discounts for even a single patient who did not achieve the desired outcome.

Assuming nobody pays for non-responders, and commercial plans pay the same price for responders as CMS, it's logical to expect best price would not be a factor. After all, there is no better price than free.

#### COMPANIES AND INSTITUTIONS MENTIONED

Harvard Pilgrim Health Care Inc., Boston, Mass.

Inovalon Holdings Inc. (NASDAQ:INOV), Bowie, Md

Molina Healthcare Inc., Long Beach, Calif.

National Institute for Health and Care Excellence (NICE), London, U.K.

Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland

Real Endpoints LLC, Westport, Conn.

University of York, York, U.K.

U.S. Centers for Medicare & Medicaid Services (CMS), Baltimore, Md.

U.S. Food and Drug Administration (FDA), Silver Spring, Md.

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BIOCENTURY TOC

McCallister, E. "Accessing miracles." BioCentury (2017)

Schaeffer, S. "Dendreon's curve ball." BioCentury (2011)

EBB & FLOW

### **SOARING KITE**

BY STEPHEN HANSEN, ASSOCIATE EDITOR

Four buysiders told BioCentury that Kite Pharma Inc. (NASDAQ:KITE) may have gotten maximum value for shareholders in its near \$12 billion takeout by Gilead Sciences Inc. (NASDAQ:GILD) given the run-up in the stock since the start of the year.

On Aug. 28, Gilead announced it will acquire Kite for \$180 per share, or about \$11.9 billion. While the deal is a modest 29% premium to Kite's Aug. 25 close of \$139.10, it is a 217% premium over its share price on Feb. 27, the day before it reported data from the pivotal Phase II ZUMA-1 trial for lead CART therapy axicabtagene ciloleucel (KTE-C19).

Kite's valuation jumped from \$3 billion to \$3.7 billion on Feb. 28 after reporting positive ZUMA-1 data, and continued to rise to \$8 billion over the next six months on the back of additional positive milestones. The most recent bump came on Aug. 8, when Kite added \$6.58 to \$120.13 after the biotech said FDA wouldn't require an advisory committee meeting for axicabtagene ahead of its Nov. 29 PDUFA date for a BLA to treat refractory aggressive non-Hodgkin's lymphoma (NHL).

According to LSP's Joep Muijrers, a long-term Kite investor, the takeout price is hard to reach unless a fair amount of value is ascribed to the rest of Kite's pipeline or a broader label for axicabtagene ciloleucel.

"The price definitely met or exceeded my expectations," Muijrers said. "But you cannot justify a \$12 billion acquisition price based only on axicabtagene ciloleucel in its current refractory indication, I think that's simply impossible."

Two buysiders who asked not to be named agreed, with one noting that the deal price gives Kite credit for success either in earlier lines of therapy or in solid tumors, both of which the buysider said remain high risk.

The other buysider said it was "a very full price" given that the risks for further development of Kite's pipeline are just as high as the clinical development risk has been for axicabtagene.

But Omega Fund's Otello Stampacchia argued that on the basis of consensus analyst estimates of \$1-\$2 billion peak sales for axicabtagene, using a common 8-9x multiple on sales means that although the price may be high for a pre-commercial company, Gilead may not have overpaid. He added that it also means there's additional upside in Kite's pipeline.

For Gilead investors, the Wednesday approval of CART therapy Kymriah tisagenlecleucel-T from Novartis AG (NYSE:NVS; SIX:NOVN) to treat pediatric and young adult acute lymphoblastic leukemia (ALL) appears to have relieved some concerns about the approvability and pricing of axicabtagene (see "Pathfinding for Access").

After adding about \$1.2 billion in market cap the day the Kite deal was announced, the bellwether added nearly \$7.2 billion on Aug. 30, the day Kymriah was approved. For the week, Gilead finished up \$9.96 (13%) to \$83.75, adding \$13 billion in market cap.

### FUND FINE-TUNING

BY STEPHEN HANSEN, ASSOCIATE EDITOR

BioMedPartners is fine-tuning its strategy for its third fund to focus more on therapeutics investments, where the firm has seen most of its biggest returns.

The Swiss VC told BioCentury BioMedInvest III has reached an interim close of about CHF100 million (\$104.7 million), following a first close of CHF75 million (\$75.1 million) in February. The firm is targeting a final close next February of CHF120-CHF150 million (\$125.7-\$157.2 million).

"THE PRICE DEFINITELY MET OR EXCEEDED MY EXPECTATIONS."

JOEP MUIJRERS, LSP

"OUR NICEST EXITS CONSISTENTLY WERE PHARMA OR BIOPHARMA EXITS."

MARKUS HOSANG, BIOMEDPARTNERS

BioMedPartners' Markus Hosang said the firm is ratcheting up its investments in therapeutics to two-thirds of the fund — from about half in its first two funds — in the hope of repeating its successes with biopharma plays. The remainder will be split between medtech and diagnostics.

"Our nicest exits consistently were pharma or biopharma exits," he told BioCentury.

Among BioMedPartners' best exits, two garnered multiples of 7x or better: vaccine play Okairos AG, which GlaxoSmithKline plc (LSE:GSK; NYSE:GSK) acquired in 2013 for €250 million (\$323 million); and the Roche (SIX:ROG; OTCQX:RHHBY) takeout of cancer and autoimmune company Glycart Biotechnology AG in 2005 for CHF235 million (\$181.5 million).

The firm is also expanding its geographical scope for the new fund to include a small number of companies in Benelux countries. It previously invested only in Switzerland and immediate neighbors Germany, France, Italy and Austria. Hosang noted the Benelux "has time and time again offered interesting opportunities."

The firm's focus remains early stage companies raising series A or B rounds and it plans to continue seeding corporate spinouts as it did with Okairos, which spun out of Merck & Co. Inc. (NYSE:MRK).

Hosang said BioMedPartners plans to invest in a total of 15-18 companies through the new fund and has already invested two. The first financing was in a  $\in$ 15 million (\$16.3 million) series A round in May for cardiovascular play Cardior Pharmaceuticals GmbH, which is developing therapies that target microRNA to treat heart failure. He expects the fund's second investment to be disclosed in early September.

The firm closed BioMedInvest I in 2003 at CHF100 million (\$74 million), and BioMedInvest II in 2009 at CHF106 million (\$104.2 million).

### ARMO'S CHINA NETWORK

#### BY VIRGINIA LI, STAFF WRITER

Chinese investors in Armo BioSciences Inc.'s \$67 million series C-1 round could help the Redwood City, Calif., company establish local partnerships and bring its lead cancer therapy to the China market.

Qiming Venture Partners led the untranched round, and was joined by fellow China-based new investors Decheng Capital, Quan Capital and Sequoia Capital. RTW Investment, also a new investor, and existing investors Kleiner Perkins Caufield & Byers, OrbiMed Advisors, DAG Ventures, NanoDimension, HBM Healthcare Investments, GV, Celgene Corp. (NASDAQ:CELG) and funds advised by Clough Capital participated in the round as well.

Qiming's Gary Rieschel told BioCentury, "What we have been doing in the U.S. is looking for best-in-class and first-in-class products that we can plug into the network Qiming has in China."

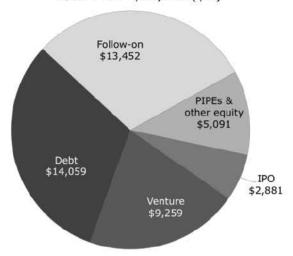
Armo is the sixth investment from Qiming's U.S. fund.

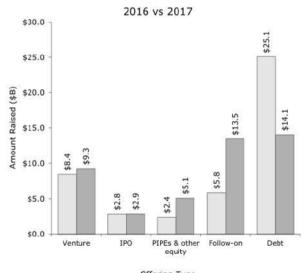
Qiming's China portfolio includes Canbridge Life Sciences Ltd., Zai Lab Ltd. and Antengene Corp., all of which in-license therapeutics from U.S. and European sources for the China market.

### MONEY RAISED IN 2017

In the last two weeks, the biotech industry raised \$626.4 million, bringing to \$44.7 billion the total raised year-to-date. In 2016, a total of \$85 billion was raised, including \$49.1 billion in debt, \$10.3 billion in follow-ons, \$3.8 billion in PIPEs and other equity, \$7.2 billion in IPOs, and \$14.7 billion in venture capital. Totals include overallotments and warrants, and are rounded to the nearest millions.

Total YTD: \$44,741 (\$M)





Offering Type



#### **COVER STORY**

#### CUTTING THROUGH RESISTANCE

Locus thinks the lesser-known CRISPR-Cas3 system could be a more powerful tool for eliminating drug-resistant bacteria than the better-known CRISPR-Cas9.

#### TARGETS & MECHANISMS

#### NECROPTOSIS STRIKES AGAIN

Necroptosis levels correlate with Alzheimer's pathology and brain size, pushing the RIPK1 pathway into the cross hairs for another CNS disorder.

#### TRANSLATION IN BRIEF

#### FATE'S KILLER MEMORY

Fate Therapeutics has revealed how it generates the NK cells in its Phase I cancer therapy Fate-NK100, and created two iPS cell-derived versions for off-the-shelf use.

#### MOUSE MODEL HERDS

The International Mouse Phenotyping Consortium publishes data on over 3,300 genes and 185 disease models.

#### GENE, SCORE, MATCH

A UCSF group is using gene expression profiles, rather than target-based screening, to match drug compounds with specific tumor types.

#### **EXTINGUISHING AVERSION**

A team from the Chinese Academy of Sciences has shown how a RACI-activated pathway extinguishes aversive memories associated with opioid withdrawal.

#### BRINGING HOME EXOSOMES

Biological Dynamics has published data demonstrating its exosome-on-a-chip diagnostic can capture viable exosomes in 30 minutes.

#### DISTILLERY

#### This week in therapeutics

This week in therapeutics includes important research findings on targets and compounds, grouped first by disease class and then alphabetically by indication.

#### This week in techniques

This week in techniques includes findings about research tools, disease models and manufacturing processes that have the potential to enable or improve all stages of drug discovery and development.

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"We have a broad portfolio, so we could help any U.S. company that is looking to establish partnerships and distribution in China," said Rieschel.

According to him, Qiming saw opportunity in the breadth of indications Armo could pursue with lead asset AM0010, a recombinant pegylated IL-10 exclusively licensed from Merck & Co. Inc. (NYSE:MRK).

In a 350-patient Phase Ib study, AM0010 as a monotherapy, and in combination with a marketed PD-1 inhibitor or chemotherapy, led to durable responses across multiple tumor types including melanoma, colorectal cancer, non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC) and pancreatic cancer. Data were reported at the American Society of Clinical Oncology (ASCO) meeting in June.

"We had been working with new investors on this financing for several months, but I think the ASCO data pushed them to act and put money in the company," said President and CEO Peter Van Vlasselaer.

AM0010 is in a Phase III study in combination with FOLFOX chemotherapy to treat metastatic pancreatic cancer. Data are expected in late 2019 or early 2020.

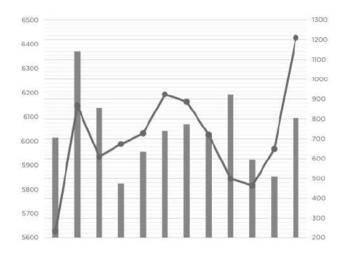
The therapy is also slated to enter Phase II testing this year in combination with an undisclosed, marketed PD-1 inhibitor to treat NSCLC and RCC.

Eventually, Armo plans to develop AM0010 in combination with its inhouse PD-1 inhibitor AM0001, which is in preclinical development.

Armo exclusively licensed AM0001 from Open Monoclonal Technology Inc., which Ligand Pharmaceuticals Inc. (NASDAQ:LGND) acquired in 2016 (see BioCentury, Feb. 15, 2016).

#### **BIOCENTURY 100 PRICE & VOLUME TREND**

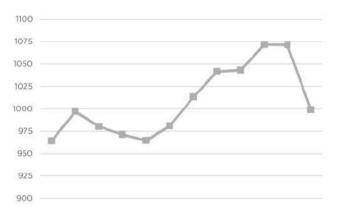
Cumulative weekly performance of 100 bioscience stocks. 12-week period. Line shows Price Level change (Left scale. Index base=1000 on May 10, 1996). Bars show cumulative volume in millions (right scale).



BioCentury tracks 857 issues that report prices and volume daily. The BioCentury 100 is a subset used to monitor price and volume trends

#### **BIOCENTURY LONDON INDEX**

Weekly change in the combined market capitalization for 14 bioscience stocks listed on the LSE or AIM, 12-week period. Index base =1000 on May 10, 1996.





#### **BIOCENTURY 100 INDICATORS**

Week ended 9/1/17

PRICES 6426.98 up 8% VOLUME 805M shrs up 58%

#### PRICE GAINS

Stocks with greatest % price increase in the week ended 9/1. (Priced above \$2; 5,000 minimum share volume)

| Company             | Ticker | \$Close   | \$Chg    | % Chg | Vol(00) |
|---------------------|--------|-----------|----------|-------|---------|
| Opiant              | OPNT   | 39,000    | 18.100   | 87%   | 5715    |
| Aptevo              | APVO   | 2110      | 0.840    | 66%   | 111039  |
| Abeona Therapeutics | ABEO   | 13.800    | 4.750    | 52%   | 114947  |
| UroGen Pharma       | URGN   | 25.290    | 7.820    | 45%   | 6765    |
| Tracon              | TCON   | 3.150     | 0.950    | 43%   | 14142   |
| Medigene            | MDG1   | €12.850   | €3.560   | 38%   | 27703   |
| Juno Therapeutics   | JUNO   | 41.920    | 11.190   | 36%   | 562195  |
| PCI                 | PCIB   | NOK26.700 | NOK7.000 | 36%   | 14809   |
| Immune Design       | IMDZ   | 11.000    | 2.850    | 35%   | 13451   |
| bluebird bio        | BLUE   | 130.850   | 33.000   | 34%   | 95735   |

#### PRICE DECLINES

Stocks with greatest % price decline (criteria as above).

| Company                | Ticker | \$Close   | \$Chg     | % Chg | Vol(00) |
|------------------------|--------|-----------|-----------|-------|---------|
| Otonomy                | OTIC   | 3.600     | -16.450   | -82%  | 578901  |
| GeNeuro                | GNRO   | €4.260    | -€8.120   | -66%  | 6184    |
| Indivior               | INDV   | 267.6p    | -145.5p   | -35%  | 223614  |
| Acorda                 | ACOR   | 21.700    | -3.450    | -14%  | 138928  |
| GNI Group              | 2160   | ¥440.000  | -¥57.000  | -11%  | 204986  |
| Xenetic                | XBIO   | 2,406     | -0.308    | -11%  | 624     |
| Aveo Pharmaceuticals   | AVEO   | 3,380     | -0.420    | -11%  | 645703  |
| Leap Therapeutics      | LPTX   | 5,630     | -0.520    | -8%   | 803     |
| Marina Biotech         | MRNAD  | 2.700     | -0.234    | -8%   | 103     |
| BoneSupport            | BONEX  | SEK24.200 | -SEK2.000 | -8%   | 600     |
| Mesoblast <sup>1</sup> | MESO   | 6.000     | -0.490    | -8%   | 82339   |

#### **VOLUME GAINS**

Greatest changes in volume above 5,000 shares.

| Company           | Ticker | Vol(00) | %Chg  | \$Close   | \$Chg    |
|-------------------|--------|---------|-------|-----------|----------|
| CanBas            | 4575   | 78008   | 7259% | ¥658,000  | ¥2.000   |
| Otonomy           | OTIC   | 578901  | 4551% | 3.600     | -16.450  |
| GeNeuro           | GNRO   | 6184    | 2169% | €4.260    | -€8.120  |
| Aptevo            | APVO   | 111039  | 1499% | 2.110     | 0.840    |
| UroGen Pharma     | URGN   | 6765    | 764%  | 25.290    | 7.820    |
| Juno Therapeutics | JUNO   | 562195  | 695%  | 41.920    | 11.190   |
| Kite Pharma       | KITE   | 421331  | 642%  | 178.050   | 38.950   |
| Opiant            | OPNT   | 5715    | 633%  | 39.000    | 18100    |
| genOway           | ALGEN  | 1723    | 621%  | €2.470    | €0.280   |
| Kuros Biosciences | KURN   | 1610    | 569%  | CHF13.900 | CHF0.750 |

1 Includes volume from Australian Stock Exchange and converted ADSs (1 ADS = 5 shares)

#### **BIOCENTURY 100 ADVANCE-DECLINE TRENDS**

| Week ended | BC100<br>Price<br>Level | BC100<br>Stocks<br>gaining | Gaining<br>vol. (00) | BC100<br>Stocks<br>declining | Declining<br>vol. (00) |
|------------|-------------------------|----------------------------|----------------------|------------------------------|------------------------|
| Aug 04     | 6026.62                 | 33                         | 2094189              | 67                           | 5170268                |
| Aug 11     | 5845.01                 | 21                         | 1790259              | 79                           | 7453097                |
| Aug 18     | 5816.90                 | 36                         | 2270212              | 64                           | 3690804                |
| Aug 25     | 5967.45                 | 81                         | 3691149              | 19                           | 1418186                |
| Sep 01     | 6426.98                 | 91                         | 7009092              | 9                            | 1041049                |

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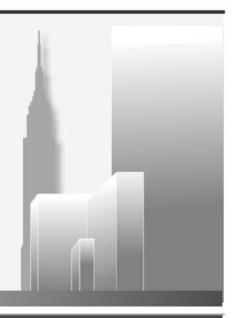
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In response to the market, NewsMakers again features a track of young, emerging companies that are developing 30 originated products in key disease areas, such as cancer, autoimmune, inflammation, gene and cell therapy. Twelve companies in the 2017 Next Wave class have raised more than \$180 million in venture capital and private equity and eight were founded within the last three years. This innovative group represents several countries, including the U.S., U.K., Canada, China and Taiwan.

Beyond the private plays, NewsMakers continues to showcase leading public biotech companies. In total, the NewsMakers' class has raised more than \$4.5 billion in capital, with more than \$2.1 billion coming since the beginning of 2015, including nearly \$800 million in 2017 alone.

### **Expanded Slate of Presenting Companies**

#### **Full Presenting Companies**

Aduro Biotech Inc. (NASDAQ:ADRO)

Adverum Biotechnologies, Inc. (NASDAQ:ADVM)

Aimmune Therapeutics Inc. (NASDAQ:AIMT)

Ascentage Pharma Group Corp. Ltd

Aslan Pharmaceuticals Pte. Ltd.

Codexis Inc. (NASDAQ: CDXS)

CTI BioPharma Corp. (NASDAQ:CTIC; Milan:CTIC)

DNAe Group Holdings Ltd.

Dynavax Technologies Corp.(NASDAQ:DVAX)

Egalet Corp. (NASDAQ:EGLT)

Eiger BioPharmaceuticals Inc. (NASDAQ:EIGR)

EIP Pharma LLC

Fulcrum Therapeutics Inc.

GlycoMimetics Inc. (NASDAQ:GLYC)

Immunicum AB (SSE:IMMU)

Innovation Pharmaceuticals Inc. (OTCQB:IPIX)

Intec Phama Ltd. (Tel Aviv:NTEC; NASDAQ:NTEC)

MEI Pharma Inc. (NASDAQ:MEIP)

Molecular Templates Inc. (NASDAQ:MTEM)

Nanobiotix S.A. (Euronext:NANO)

Rebiotix Inc.

Spectrum Pharmaceuticals Inc. (NASDAQ:SPPI)

Sutro Biopharma Inc.

Synlogic Inc.

Synthetic Biologics Inc. (NYSE-M:SYN)

Tyme Technologies Inc. (NASDAQ:TYME)

WuXi NextCode Genomics Inc.

#### Next Wave Presenting Companies

Akonni Biosystems Inc.

Akriveia Therapeutics LLC

F-star Biotechnology Ltd.

Generon (Shanghai) Corp. Ltd.

Kezar Life Sciences

Lin Bioscence

Medeor Therapeutics Inc.

Northern Biologics Inc.

Palladio Biosciences Inc. Sigilon Therapeutics Inc.

Tactiva Therapeutics Inc.

Wellesley Pharmaceuticals LLC

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Since 2014, the BioCentury China Healthcare Summit has been singularly focused on how China is building its Bridge to Innovation. Now in its fourth year, the 2017 Summit examines where China is positioned to lead among global innovators, and asks whether the policy, regulatory, financial and management conditions are finally in place to make these aspirations a reality. Why should you attend?



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- 2 TAKE A DEEP DIVE into next-generation genomics, biomarkers and diagnostics as leading executives, researchers and investors determine steps needed for China to become a leader in Gx. Dx and beyond.
  - (Speakers include: Simone Fishburn, Ph.D., Editor, BioCentury Innovations; Mao Mao Ph.D., Chief Scientific Officer, BGI Genomics; Ruilin Zhao, Ph.D., General Manager, Greater China, Illumina Inc.; Hongye Sun, Ph.D., Chief Technology Officer, WuXi NextCode; Nisa Leung, Managing Partner, Qiming Ventures)
- 3 IDENTIFY China market trends and business imperatives for biopharma companies through an exclusive conference report prepared by our Insights Partner, McKinsey & Co.
  - (Presented by Gaobo Zhou, Partner & Co-Leader, China Healthcare Practice, McKinsey & Co.)
- DETERMINE which CFDA reforms and life sciences policy changes in China are likely to succeed and how innovators can respond to a rapidly changing landscape.

- 5 LEARN how China's next generation of startups is shifting away from "me too" or "me better" products to pursue global innovation. (Session Chair: Steve Yang, Ph.D., EVP & COO, WuXi Apptec)
- 6 DEBATE where China can become a first mover in artificial intelligence-driven approaches across the healthcare value chain. (Speakers include: Yingrui LI, Ph.D., Co-Founder & Chief Scientist, iCarbonX; Stanley Li, M.D., Founder, DXY; Alex Zharvoronkov, Ph.D., Co-Founder & CEO, In Silico Medicine; Serafim Batzoglou, Ph.D., VP, Applied & Computational Biology, Illumina Inc.; Andrea de Souza, Global Business Development Lead, Healthcare Al, NVIDIA Corp.; Laura Nelson Carney, Senior Research Analyst, Asia Pacific Healthcare, AB Bernstein)
- 7 CELEBRATE outstanding individuals and companies for their achievement and contribution to the local healthcare ecosystem during the BayHelix China Healthcare Awards lunch ceremony.
- 8 NETWORK with China and global peers in an intimate VIP-only event reserved for senior-level executives, investors and scientists.

Attendance at this VIP-only meeting is restricted to senior executives, scientists and investors. Seating is limited, so register today to reserve your seat.

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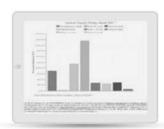
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**MORE INFO** 

Sent: Mon, 20 Nov 2017 22:07:05 +0000

To: Collins, Francis (NIH/OD) [E]
Subject: Great WP Profile!!!

Awesome piece! M.

 Sent:
 Thu, 14 Sep 2017 00:55:12 +0000

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Jan Lundgren

Francis - FYI only, Jan will join Steve Paul and Richard Hodes in a conversation on AD, and other aging research interests at the FNIH Board dinner on the 18th of October. So sorry you will be away - if you happen to be around, please join us for dinner at the Cloisters. M.

**Sent:** Tue, 24 Oct 2017 18:48:29 +0000 **To:** Baden, Elizabeth (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E];Steve Paul
Subject: Memo for the NIH Steering Committee
Attachments: Enhanced NIH Support of the FNIH.pdf

Dear Members of the NIH-FNIH Steering Committee,

Per you request, attached please find a memorandum requesting that NIH consider providing FNIH the full appropriation provided by law. FNIH is committed to continue to support the NIH and to work closely with this committee and NIH leadership in support of your priorities.

Many, many thanks for your consideration. All the best, Maria







 Sent:
 Thu, 21 Sep 2017 17:36:50 +0000

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Wholley, David (FNIH) [T]

Subject: Opioids

Francis, David just updated me on the where we are on the opioids planning. Turns out the funds we got as a one-time contribution for PACT were from the 2016 NIH approps. Therefore, you can, in principle, provide us up to \$250K from 2017 funds. If it is 2018 funds, let's discuss a bit more. M.

Freire, Maria (FNIH) [T] From:

Wed, 2 Aug 2017 17:44:16 +0000 Sent: Collins, Francis (NIH/OD) [E] To:

Subject: Quick thought

Hi Francis. Just met with David, who mentioned he had a call with Rebecca this morning on opioids. She (b) (5) (b) (5) mentioned that

(b) (5) Cheers, M.

**Sent:** Wed, 6 Sep 2017 03:37:36 +0000 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: BioCentury on biopharma's social contract

Indeed - and about time.

On Sep 5, 2017, at 4:54 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Wow, that is a pretty powerful exhortation!

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, September 05, 2017 5:12 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Fwd: BioCentury on biopharma's social contract

Francis, in case you did not see this. It is a very interesting read! M.

Begin forwarded message:

From: "Steve Usdin" < susdin@biocentury.com >
To: "Freire, Maria (FNIH) [T]" < mfreire@fnih.org >
Subject: BioCentury on biopharma's social contract

Maria, I thought this might be of interest.

Hope all is well, Steve

Steve Usdin
Washington Editor, BioCentury
Susdin@BioCentury.com

Tel. 202-462-9582 Mobile (b) (6)

Notice: This communication (including any attachments) constitutes an electronic communication within the meaning of the Electronic Communications Privacy Act, 18 USC 2510, and its disclosure is strictly limited to the recipient(s) intended by the sender of this message. This communication (including any attachments) contains proprietary information, is protected under U.S. and foreign copyright and other intellectual property law, and may contain confidential material for the sole use of the intended recipient. Any unauthorized review, use, dissemination, copying or distribution of this communication (including any attachments), or any of their respective contents, is strictly prohibited. If you are not the intended recipient, please contact the sender by return email and destroy all copies of the original message.

| From: Sent: To: Cc: Gretchen (NIH/OD) [E];E Subject:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Freire, Maria (FNIH) [T] Tue, 12 Dec 2017 01:37:4 Collins, Francis (NIH/OD) McManus, Ayanna (NIH/O Balthaser, Robert (FNIH) [The Check presentation of                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | [E]<br>DD) [E];Diane Baker                                                                                                                   | (b) (6));Wood,                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| ~                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | *                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | d to seeing you and Diane. M                                                                                                                 |                                                     |
| To the control of the | :56 PM, Collins, Francis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                              | (b) (6) wrote:                                      |
| Hi Maria,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                              |                                                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | e by 4:30 PM, unless the of the learning the | opioid PPP meeting runs way oversday afternoon).                                                                                             | er time (which seems                                |
| Diane is coming too.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                              |                                                     |
| I've seen the previous p<br>(and his Dad, and his ca                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | v Lee – amazing kid, and I'll be d                                                                                                           | elighted to meet him                                |
| See you then,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                              |                                                     |
| Francis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                              |                                                     |
| 38, 350                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | er 11, 2017 5:42 PM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | a trait title gib                                                                                                                            |                                                     |
| Hi Francis. Tomorrow a will help move the need                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | on opioids ought to be very inte                                                                                                             | resting and hopefully                               |
| we will have a small "ch<br>Cure to FNIH at 4:30pm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | eck-handing" ceremony o<br>. It would be great if you oversized check (we are ver                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | use on Wednesday – that is awe<br>f an additional contribution of \$<br>could be there – although we kn<br>ry careful about that!). The fund | 100,000 by <i>Driven to</i><br>ow well no NIHer can |
| You may recall that <i>Driv</i> research. It was founde                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | d by Andrew Lee,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | tion that donated \$200,000 last out cars and takes his orange Nis.                                                                          | (b) (6)                                             |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | awareness and funds for                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | kidney cancer research. Here is driventocure.org/programs.htm                                                                                | a link to his story,                                |

| Andrew and his family and Marston will be there | . I have not heard from Jim Gilman yet. | Any chance |
|-------------------------------------------------|-----------------------------------------|------------|
| you can be there? Cheers, M.                    |                                         |            |
|                                                 |                                         |            |

 Sent:
 Sat, 18 Nov 2017 01:36:07 +0000

 To:
 Burklow, John (NIH/OD) [E]

 Cc:
 Collins, Francis (NIH/OD) [E]

Subject: Re: FNIH won a Gold Stevie Award!

Thanks John. We have an awesome team, great Board and the FABULOUS NIH! This is being broadcast globally. How cool to get it. I am humbled and proud!

On Nov 17, 2017, at 8:33 PM, Burklow, John (NIH/OD) [E] (b) (6) wrote:

Congratulations, Maria!

Sent from my iPhone

On Nov 17, 2017, at 8:28 PM, Freire, Maria (FNIH) [T] < mfreire@fnih.org > wrote:

Just now in NYC for Organization of the Year - Government or Non Profit- More than 10 Employees! Sooo honored!!!

<IMG 1435.JPG>

**Sent:** Mon, 17 Jul 2017 16:20:51 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: Following up

Hi Francis,

The meeting with Betsy, Jeff and the new CMO, who joined by phone, was constructive. We made it clear that we were going to allow the LOA to expire.

As we agreed, we also said that they could send a donation to the gift fund or await a call from us if/when there is an appropriate project for funding. The bottom line is that the proposal must come from NIH not from NFL and that the relationship has to be arms-length. Interestingly, there is substantial interest in opioids.

Happy to debrief further, M.

----Original Message----

From: Collins, Francis (NIH/OD) [E] Sent: Saturday, July 15, 2017 5:10 PM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: RE: Following up

Hi Maria,

Yes, I did speak with Larry and Carrie, sorry I failed to pass that on -- they were OK with the gift fund as an alternative plan if NFL still wants to make a donation. Presumably they would want these funds targeted towards research on sports injuries, but the terms would make it clear that there would be no further input from NFL.

They were also in sync with you and me that any further proposals for medical research that NFL might support would need to come from NIH, not from NFL.

Thanks, let me know how your Monday meeting goes.

Francis

----Original Message----

From: Freire, Maria (FNIH) [T]

Sent: Saturday, July 15, 2017 10:38 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Following up

Francis, did you get a chance to talk to Larry and Carrie about support for the gift fund, if the opportunity arises? Best, M.

**Sent:** Sat, 15 Jul 2017 17:11:51 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Following up

Thanks so much, Francis. Yes, I will let you know. Stay cool! M.

```
> On Jul 15, 2017, at 5:10 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote: > Hi Maria, >
```

> Yes, I did speak with Larry and Carrie, sorry I failed to pass that on — they were OK with the gift fund as an alternative plan if NFL still wants to make a donation. Presumably they would want these funds targeted towards research on sports injuries, but the terms would make it clear that there would be no further input from NFL.

> They were also in sync with you and me that any further proposals for medical research that NFL might support would need to come from NIH, not from NFL.

> Thanks, let me know how your Monday meeting goes.

> Francis

> -----Original Message-----> From: Freire, Maria (FNIH) [T]

> Sent: Saturday, July 15, 2017 10:38 AM

> To: Collins, Francis (NIH/OD) [E] (b) (6)

> Subject: Following up

>

> Francis, did you get a chance to talk to Larry and Carrie about support for the gift fund, if the opportunity arises? Best, M.

**Sent:** Mon, 17 Jul 2017 17:05:49 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burklow, John

(NIH/OD)[E]

Subject: RE: Following up

On a totally unrelated topic, we just got news that we got, yet again, the top 4-star rating from Charity Navigator with a score of 96.2%. In their own words:

"Your organization is the 11th highest rating for the Medical Research cause area, and 1st among Biomedical Research organizations."

Pretty darn good! Smiling, M.

----Original Message----

From: Collins, Francis (NIH/OD) [E] Sent: Monday, July 17, 2017 4:58 PM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Cc: Tabak, Lawrence (NIH/OD) [E] (b) (6) Wolinetz, Carrie (NIH/OD) [E]

(b) (6); Burklow, John (NIH/OD) [E] (b) (6)

Subject: RE: Following up

Thanks, Maria.

----Original Message----

From: Freire, Maria (FNIH) [T] Sent: Monday, July 17, 2017 4:21 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: RE: Following up

Hi Francis,

The meeting with Betsy, Jeff and the new CMO, who joined by phone, was constructive. We made it clear that we were going to allow the LOA to expire.

As we agreed, we also said that they could send a donation to the gift fund or await a call from us if/when there is an appropriate project for funding. The bottom line is that the proposal must come from NIH not from NFL and that the relationship has to be arms-length. Interestingly, there is substantial interest in opioids.

Happy to debrief further, M.

----Original Message----

From: Collins, Francis (NIH/OD) [E] Sent: Saturday, July 15, 2017 5:10 PM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: RE: Following up

Hi Maria,

Yes, I did speak with Larry and Carrie, sorry I failed to pass that on -- they were OK with the gift fund as an alternative plan if NFL still wants to make a donation. Presumably they would want these funds targeted towards research on sports injuries, but the terms would make it clear that there would be no further input from NFL.

They were also in sync with you and me that any further proposals for medical research that NFL might support would need to come from NIH, not from NFL.

Thanks, let me know how your Monday meeting goes.

Francis

----Original Message----

From: Freire, Maria (FNIH) [T]

Sent: Saturday, July 15, 2017 10:38 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Following up

Francis, did you get a chance to talk to Larry and Carrie about support for the gift fund, if the opportunity arises? Best, M.

Sent: Tue, 18 Jul 2017 19:46:52 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: Re: More exciting FNIH news...

Thanks, Francis. I know it is all about the people around me. How lucky I am to have great staff, a terrific Board and an awesome NIH Director! M.

On Jul 18, 2017, at 7:43 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Double congrats and hearty huzzahs to Maria and all of FNIH!

Francis

From: Meltzer, Abbey (FNIH) [T]
Sent: Tuesday, July 18, 2017 4:04 PM
To: Froire, Maria (FNIH) [T] confroire (FNIH)

To: Freire, Maria (FNIH) [T] < mfreire@fnih.org>; Steve Paul < steve@vygr.com>; bloomgardenk@ruderfinn.com; Buffy Cafritz (b) (6) >; Donovan, James

(james.donovan@gs.com) <james.donovan@gs.com>; (b) (6);

tom@mindstronghealth.com; Judy Kovler (b) (6) Ronald Krall

(b) (6); Freda.Lewis-Hall < Freda.Lewis-Hall@pfizer.com >; Edison.Liu@jax.org; Joel Marcus

<tcharles@bayberryfinancial.com>; marty@amedconsulting.com; (b) (6) Max Coslov

<Max.Coslov@edmondjsafra.org>; Lori Franklin (b) (6) (6)

Seigel, Fred <<u>FSeigel@beaconcapital.com</u>>; esigal2 <<u>esigal@focr.org</u>>; Sol Snyder (<u>ssnyder@jhmi.edu</u>)

<ssnyder@jhmi.edu>; Nina Solarz (b) (6); Steenberg, Russell

<russ.steenberg@blackrock.com>; Stoffels, Paul [JJCUS] (PStoffe4@its.jnj.com) <PStoffe4@its.jnj.com>;

Thier, Samuel Osiah, M.D. < STHIER@PARTNERS.ORG >; LBrady@drexelmed.edu; Ann Iurie

<ann@annlurie.com>; john.porter@hoganlovells.com; Collins, Francis (NIH/OD) [E]

(b) (6)

Cc: James, Stephanie (FNIH) [T] < sjames@fnih.org>; Wholley, David (FNIH) [T] < dwholley@fnih.org>; Wolf-Rodda, Julie (FNIH) [T] < iwolf-rodda@fnih.org>; Klock, Kevin (FNIH) [T] < kklock@fnih.org>;

Balthaser, Robert (FNIH) [T] <rbalthaser@fnih.org>

Subject: More exciting FNIH news...

#### STRICTLY CONFIDENTIAL until September 22, 2017

Dear Members of the FNIH Board of Directors,

In other exciting FNIH news, I am pleased to inform you that we recently learned that Dr. Maria Freire was selected as one of the Washington Business Journal's 2017 Women Who Mean Business Award Winners! In its 14th year of the program, they said this year was the *most* difficult selection the judges have encountered with hundreds of nominations pouring in from exceptional women all over our region.

Dr. Freire will accept the award at a ceremony in Washington in early November, and we ask that you keep this news confidential until September 22, 2017 when the special publication announcing the winners will be published.

Please join me in congratulating Dr. Freire as we look forward to celebrating this accomplishment and promoting her award in the coming months!

Best, Abbey

Abbey Meltzer
Director of Communications
Foundation for the National Institutes of Health (301) 435-4103
finih.org

Learn more about the FNIH in our 2016 Annual Report: fnih.org/AnnualReport.

From: Freire, Maria (FNIH) [T] Sent: Tuesday, July 18, 2017 12:00 PM To: Steve Paul <steve@vygr.com>; (b) (6); bloomgardenk@ruderfinn.com; Buffy Cafritz (b) (6); Donovan, James (james.donovan@gs.com) <james.donovan@gs.com>; (b) (6); tom@mindstronghealth.com; Judy Kovler (b) (6); Ronald Krall (b) (6); Freda.Lewis-Hall < Freda.Lewis-Hall@pfizer.com>; Edison.Liu@jax.org; Joel Marcus < jmarcus@are.com>; Steve Mayer (b) (6); Charles, Tracey <tcharles@bayberryfinancial.com>; marty@amedconsulting.com; (b) (6); Max Coslov (b)(6)<Max.Coslov@edmondjsafra.org>; Lori Franklin Seigel, Fred <FSeigel@beaconcapital.com>; esigal2 <esigal@focr.org>; Sol Snyder (ssnyder@jhmi.edu) <ssnyder@jhmi.edu>; Nina Solarz (b) (6); Steenberg, Russell <russ.steenberg@blackrock.com>; Stoffels, Paul [JJCUS] (PStoffe4@its.jnj.com) <PStoffe4@its.jnj.com>; Thier, Samuel Osiah, M.D. <STHIER@PARTNERS.ORG>; LBrady@drexelmed.edu; Ann Iurie <ann@annlurie.com>; john.porter@hcganlovells.com; Collins, Francis (NIH/OD) [E] (b)(6)Cc: James, Stephanie (FNIH) [T] <siames@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Wolf-Rodda, Julie (FNIH) [T] < jwolf-rodda@fnih.org>; Klock, Kevin (FNIH) [T] < kklock@fnih.org>; Meltzer, Abbey (FNIH) [T] <ameltzer@fnih.org>; Balthaser, Robert (FNIH) [T] <rbalthaser@fnih.org>; Burklow, John (NIH/OD) [E] (b) (6); Goldie, Christina (FDA/OC) (b) (6) > Subject: FNIH receives Charity Navigator's top rating!

PS (970) 1370 (370)

Dear Members of the FNIH Board of Directors,

It is with great pleasure that I let you know that we have just been informed by Charity Navigator, America's largest independent charity evaluator, that once again the FNIH has received a **4-star rating** (the highest it bestows) AND that we are the **#1 ranked charity among Biomedical Research Organizations**.

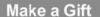
-

FNIH is featured on the Charity Navigator website under <u>4-star charities</u>. Please be on the lookout for an e-blast about the news and help us spread the word far and wide.

Thank you for all your help and support; we could not have done it without you!

All the best, Maria

From: Freire, Maria (FNIH) [T] Fri, 29 Sep 2017 03:17:52 +0000 Sent: Collins, Francis (NIH/OD) [E] To: Subject: Re: President Dr. Maria Freire Wins Washington Business Journal's Women Who Mean Business Award Thank you! But, as we know, it is all about having a great team, (b) (6) wrote: On Sep 28, 2017, at 10:14 PM, Collins, Francis (NIH/OD) [E] Wow, congrats, Maria - very well deserved! Francis From: Burklow, John (NIH/OD) [E] Sent: Thursday, September 28, 2017 10:59 AM To: Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6) Hallett, Adrienne (b) (6) (NIH/OD) [E] Subject: Fwd: President Dr. Maria Freire Wins Washington Business Journal's Women Who Mean **Business Award** FYI Sent from my iPhone Begin forwarded message: From: Foundation for the National Institutes of Health < FNIH@FoundationforNIH.org> Date: September 28, 2017 at 10:19:05 AM EDT To: "John T. Burklow" Subject: President Dr. Maria Freire Wins Washington Business Journal's Women Who Mean Business Award **Reply-To:** <FNIH@FoundationforNIH.org>





# FNIH President Dr. Maria Freire Wins Washington Business Journal's Women Who Mean Business Award



The FNIH is proud to announce that President and Executive Director Maria C. Freire, Ph.D., has won a <u>Washington Business</u> <u>Journal Women Who Mean</u> <u>Business Award</u>. Now in its 14th year, this prestigious award honors the Washington, D.C.

metropolitan area's most influential business women across every industry and profession. At the awards reception on November 1, 2017, Dr. Freire will be recognized alongside other honorees who are blazing a trail for women and making a difference in the community.

"We are delighted that Maria has been recognized as an outstanding woman in business by the *Washington Business Journal*," said Steven M. Paul, M.D., FNIH Chairman of the Board. "Maria is a tenacious and exemplary leader who has shaped the FNIH into the go-to organization for the creation of biomedical public-private partnerships and a model for other foundations. The Board of Directors and FNIH staff are honored to work alongside her each day to make breakthrough biomedical discoveries possible."



Click here to learn more about Dr. Freire and the Women Who Mean Business Awards.

## In Case You Missed It

The FNIH Honors Longstanding Partners Richard J. Hodes, M.D., and Eli Lilly & Company with Charles A. Sanders, M.D., Partnership Award



Lilly

The FNIH is proud to recognize Richard J. Hodes, M.D., Director of the National Institute on Aging (NIA), an institute of the National Institutes of Health (NIH), and Eli Lilly & Company (Lilly) as recipients of the second annual Charles A. Sanders, M.D., Partnership Award.

#### Learn More

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Foundation for the National Institutes of Health 9650 Rockville Pike, Bethesda, MD 20814

**Sent:** Wed, 2 Aug 2017 22:56:42 +0000 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Quick thought

| -  | 72075 |    |    |    |
|----|-------|----|----|----|
| Fa | nt    | 28 | 11 | CI |

| On Aug 2, 2017, at 6:48 PM, Collins, Francis (NIH/OD)                                                       | [E] (b) (6) wrote: |
|-------------------------------------------------------------------------------------------------------------|--------------------|
| Point well taken.                                                                                           | (b) (5)            |
| From: Freire, Maria (FNIH) [T]                                                                              |                    |
| Sent: Wednesday, August 02, 2017 1:44 PM  To: Collins, Francis (NIH/OD) [E] (b) (6)  Subject: Quick thought |                    |
| Hi Francis. Just met with David, who mentioned he had a call mentioned that                                 | (b) (5)            |
|                                                                                                             | (b) (5)            |
| (b) (5) Cheers, M.                                                                                          |                    |

 Sent:
 Wed, 5 Jul 2017 16:40:04 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: RE: Tempus

Very helpful - thank you!

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, July 05, 2017 4:39 PM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: RE: Tempus

Yes. I met David at a Milken meeting and was impressed with what he told me about Tempus. I invited him to visit with Warren Kibbe at NCI about a month ago. I'm told that went well, and Warren was impressed (you might want to check with him).

David is scary smart and pretty aggressive in his insistence on doing things at light speed. (b) (5)

FC

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, July 05, 2017 1:23 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Tempus

Hi Francis. Do you know David Lefkofsky (of Groupon fame) and his company Tempus? They use machine learning and genomic sequencing on tumors to "build the infrastructure to modernize cancer treatment" for personalized medicine. Confidentially,

(b) (6). M.

**Sent:** Mon, 20 Nov 2017 15:40:40 +0000 **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: The FNIH and Dr. Freire Win Gold at the 2017 Stevie Awards!

Thanks Francis! Those were nice, but not the more important. The FNIH award was the main event for me!

From: Collins, Francis (NIH/OD) [E]

Sent: Monday, November 20, 2017 10:38 AM
To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: FW: The FNIH and Dr. Freire Win Gold at the 2017 Stevie Awards!

Wow, I didn't know about the awards that were specifically given to YOU! Congratulations, Maria!!!

#### Francis

From: Meltzer, Abbey (FNIH) [T]

Sent: Monday, November 20, 2017 10:24 AM

To: Steve Paul <<u>steve@vygr.com</u>>; Deeda Blair (b) (6) >; Kathy Bloomgarden

<bloomgardenk@RuderFinn.com>; Buffy Cafritz <flippado@aol.com>; Donovan, James

(james.donovan@gs.com) <james.donovan@gs.com>; (b) (6);

tom@mindstronghealth.com; Judy Kovler (b) (6) >; Ronald Krall (b) (6);

Freda.Lewis-Hall Freda.Lewis-Hall@pfizer.com>; edison.liu@jax.org; Joel Marcus jmarcus@are.com>;

Steve Mayer (b) (6); mchateauneuf@bayberryfinancial.com; marty@amedconsulting.com; (b) (6); max.coslov@edmondjsafra.org;

(b) (6); Seigel, Fred <FSeigel@beaconcapital.com>; esigal2 <esigal@focr.org>; Sol

Snyder (ssnyder@jhmi.edu) <ssnyder@jhmi.edu>; Nina Solarz

russ.steenberg@blackrock.com; PStoffe4@its.jnj.com; Thier, Samuel Osiah, M.D.

<STHIER@PARTNERS.ORG>; lwb23@drexel.edu; ann@annlurie.com; pwalsh@jhmi.edu;

John.Porter@hoganlovells.com; Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: The FNIH and Dr. Freire Win Gold at the 2017 Stevie Awards!

Dear Members of the FNIH Board of Directors,

I am delighted to inform you that the FNIH won the 2017 Gold Stevie Award for **Organization of the Year** in the nonprofit category. The Stevie Awards are considered the world's premier business awards and one of the most coveted prizes around the globe. This is enormous validation of the mission-driven hard work of the staff and all of you. Thank you!

To add to the recognition, Dr. Freire received the Gold Stevie Award for **Woman of the Year** and the Bronze Award for **Female Executive of the Year** in the nonprofit categories! We will be sending out a press release shortly.

As Dr. Freire said to the staff this morning, "We should be proud and very pleased and not complacent – what will we do for an encore?!"

Thank you again for all of your support. Happy Thanksgiving to all!

Best, Abbey

We've moved! Please find our new address below.
Abbey Meltzer
Director of Communications
Foundation for the National Institutes of Health
(301) 435-4103
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.

**Sent:** Mon, 11 Sep 2017 17:58:23 +0000 **To:** Collins, Francis (NIH/OD) [E]

Cc: McManus, Ayanna (NIH/OD) [E];Klock, Kevin (FNIH) [T];Sepulveda, Dorina (FNIH)

[T]

Subject: Special Purpose Vehicle Meeting

Hi Francis,

As I mentioned during our meeting, the Subcommittee of the FNIH Board that is reviewing special purpose vehicles (SPVs) will meet in New York City on October 16 from 10am – 3pm at the Alexandria Center for the Life Sciences. As a Member of our Board who is very interested in this discussion, I hope you will be able to join us. Please note that invitation is personal, with no alternates or additions.

The Alexandria Center is located at 450 East 29<sup>th</sup> Street, 2<sup>nd</sup> Floor (Apella Suite 208), New York, NY 10016.

For your reference, below is the list of the FNIH Board Members that will participate, you can find their bios on our website (https://fnih.org/about/directors)

Russ Steenberg, co-chair Steve Mayer, co-chair Ron Krall Joel Marcus Steve Paul Ellen Sigal Paul Stoffels

Aron Betru and Chris Lee from the Milken Institute will present their proposal for Creative Approaches to Financing Faster Cures. This will be followed by discussion and a presentation by Paul Stoffels on SPV models that J&J has explored.

Please let me know if you can come; it would be very helpful to have you there to join the discussion.

Best, Maria

 Sent:
 Wed, 5 Jul 2017 13:23:13 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Tempus

Hi Francis. Do you know David Lefkofsky (of Groupon fame) and his company Tempus? They use machine learning and genomic sequencing on tumors to "build the infrastructure to modernize cancer treatment" for personalized medicine. Confidentially, (b) (4) M.

**Sent:** Fri, 23 Mar 2018 18:57:23 +0000 **To:** Collins, Francis (NIH/OD) [E]

Cc: Tabak, Lawrence (NIH/OD) [E]; Wholley, David (FNIH) [T]

Subject: A thought

## Francis,

In the new spending bill companies need to match NIH funds with cash or in-kind if they receive funding. When the companies are small, like in the projects Nora runs, they usually do not have much cash but they could give equity. FNIH can hold equity. Just a thought, M.

**Sent:** Wed, 21 Mar 2018 14:21:40 +0000

To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie

(NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E]; Wholley, David (FNIH) [T]

Subject: AMP OD - Nice editorial

Attachments: Lancet Editorial AMP PD March 2018.pdf

Francis – in case you did not see The Lancet editorial. Yay!!! M.

# Accelerating research for Parkinson's disease



Despite considerable ongoing translational and clinical research efforts, no disease-modifying drugs have been approved for Parkinson's disease. The Accelerating Medicines Partnership Parkinson's disease (AMP PD) programme, launched on Jan 30, 2018, is the most ambitious initiative so far to find a cure for Parkinson's disease. Formed by the US National Institutes of Health (NIH), the US Food and Drug Administration (FDA), five biopharmaceutical and life science companies, and one non-profit organisation, this partnership is focused on discovering novel therapeutic targets and on developing biomarkers to help validate existing therapeutic targets for Parkinson's disease.

Over the past decade, the neurology community has made strides in establishing of strategies for the standardised collection of biosamples from individuals with Parkinson's disease, through programmes such as the Michael J Fox Foundation Parkinson's Progression Markers Initiative and its complementary BioFIND observational study, the US National Institute of Neurological Disorders and Stroke (NINDS) Parkinson's Disease Biomarkers Program, and the Harvard Biomarker Study. These initiatives have highlighted shared interest between public and private organisations and the data being generated present an opportunity to drive biomarker development more intensively than to date for translation into more effective therapies. The AMP PD programme is being run by the Foundation for the NIH, a non-profit organisation set up by the US Congress to facilitate alliances with public and private institutions in support of the NIH mission. The Foundation will manage the partnership with GlaxoSmithKline, the Michael J Fox Foundation, NINDS, Pfizer, Sanofi, Celgene, Verily Life Sciences, and the FDA, and coordinate the pledged investment of US\$ 24 million over 5 years. A knowledge portal will be established to store and enable access to both raw and analysed datasets, such as whole genome sequences, RNA sequence data, and clinical datasets generated from existing longitudinal cohorts. Further data will be added from ongoing large-scale omics projects.

The first stage of the programme, expected to be completed within 18 months of the launch, will establish a framework for AMP PD by creating working groups, developing the knowledge portal, harmonising clinical data across cohorts, and generating whole transcriptome RNA sequence data with the goal of identifying targets and pathways altered by disease progression. Stage 2, anticipated to take 3 years, will build upon this framework by pursuing additional large-scale biomarker discovery (eg, extracellular RNA, proteomics, and metabolomics) for patient stratification, monitoring of disease progression, and determination of prognosis. A further aim is to do single-cell RNA sequence analyses to potentially enable the identification of common signatures between CSF, plasma, and brain tissue. The final stage will entail replication of results for the most promising biomarkers identified in stage 2 and will allow the addition of further omics approaches if technologies move forward during the programme. Although AMP PD will begin this work with data that have already been collected from longitudinal cohorts, incorporation of additional data from two phase 3 clinical trials in patients with early Parkinson's disease is anticipated to accelerate progress: the Study of Urate Elevation in Parkinson's Disease, Phase 3 (SURE-PD3; NCT02642393), a double-blind placebo controlled trial to determine whether oral inosine slows clinical decline, which is due to complete in 2020; and the Efficacy of Isradipine in Early Parkinson Disease (STEADY-PD3; NCT02168842), a double-blind, placebo-controlled study, which is about to be completed. The knowledge portal will enable not only the deidentified clinical data from these trials and others to be shared broadly, but also the research community to participate in and share the analysis of biosamples collected during such studies.

Sharing results from analyses of phase 3 data via the knowledge portal will provide the opportunity to conduct analyses on a scale that could not be performed by a single partner alone. The AMP PD knowledge portal will enable use of data science solutions and disease modelling to further understanding of the pathogenesis of Parkinson's disease. Bringing together the collective capabilities and resources across public and private sectors offers the best opportunity to identify and address challenges in early stage drug development and thus the best opportunity for finding a cure. 

The Lancet Neurology



For more on the NIH
Accelerating Medicines
Partnership see https://www.
nih.gov/research-training/
accelerating-medicinespartnership-amp

For more on the **NIH mission** see https://www.nih.gov/about-nih/ what-we-do/mission-goals

**Sent:** Tue, 23 Jan 2018 15:36:48 +0000

To: Collins, Francis (NIH/OD) [E];Gottesman, Michael (NIH/OD) [E];Gilman, James

(NIH/CC/OD) [E]

Cc: Burklow, John (NIH/OD) [E];Tountas, Karen (FNIH) [T];Meltzer, Abbey (FNIH) [T]

**Subject:** Announcing the 2018 Trailblazer Prize!

Good morning Francis, Michael and Jim - we are very glad you are back in business!

I am very pleased to inform you that a few minutes ago the FNIH announced a new prize (yes, Francis, we changed it to prize - ©) – the Trailblazer Prize for Clinician Scientists.

It is our strong hope and intent that NIH clinician scientists that meet the prize parameters will be nominated. We will work with Larry and his staff to make sure this prize is among those NIH staff can accept.

Here is the press release: <a href="https://fnih.org/news/press-releases/foundation-nih-opens-nominations-inaugural-trailblazer-prize-clinician-scientists">https://fnih.org/what-we-do/current-lectures-awards-and-events/trailblazer-prize</a>.

Please feel free to widely share the links. We are very excited about this prize – it will shine a light on a group of people whose work is absolutely critical for medial research. Cheers, Maria

**Sent:** Mon, 19 Mar 2018 17:02:59 +0000 **To:** Koob, George (NIH/NIAAA) [E]

Cc: Collins, Francis (NIH/OD) [E];Steve Paul;Klock, Kevin (FNIH) [T];Wolf-Rodda, Julie

(FNIH) [T]

Subject: FNIH Letter Concerning Moderate Drinking Study

Attachments: FNIH Letter to NIAAA re Moderate Drinking Study 180319.pdf

Dear George,

Please find attached a letter from the FNIH concerning the Health Effects of Moderate Drinking study. The hardcopy of this letter will arrive at your office shortly. We look forward to hearing from you at your earliest convenience.

Best, Maria



 Sent:
 Fri, 2 Feb 2018 19:53:43 +0000

 To:
 Collins, Francis (NIH/OD) [E]

Cc: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Wholley, David

(FNIH) [T];Klock, Kevin (FNIH) [T] **Subject:** Follow-up

Hi Francis. **(b) (5) (b) (5)**  Best, Maria

 Sent:
 Fri, 12 Jan 2018 10:42:18 +0000

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Wolinetz, Carrie (NIH/OD) [E]

Subject: Food for thought

#### Morning Francis.

I have been thinking about donations and how they happen. In my experience, it is like a courtship: it takes time and during this time a strong relationship needs to develop. The larger the amount, the longer it takes. In fact, many times you get smaller donations along the way, which starts establishing trust.

As the relationship develops, one gets to know the donors and what is of interest to them. For example, I was able to get \$10M from Bloomberg for Lasker after 3 years of work and the good offices of Al Sommer (and several Nobel Prize Winners). We also renamed the prize, of course.

The same thing happens on the donors' side: they get to know and trust the recipient and become intimately involved with the project. I bet you that when buildings get funded, the plans are reviewed by those whose name they bear. At an institutional level, we see this all the time, as you well know - just think Verily and AMP PD.

My sense is that it in highly unlikely to have any large commitment - or even a commitment - come from a first-time meeting. It is more likely that it be the beginning of a long process. While meeting donors in their turf is a sign of good will, a sophisticated international donor travels to the US often.

Best, M.

**Sent:** Tue, 13 Mar 2018 12:42:24 +0000

To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie

(NIH/OD) [E]

Cc: Klock, Kevin (FNIH) [T]; Wholley, David (FNIH) [T]; Gonzalez-Cos, Francisco (FNIH)

[T];Sepulveda, Dorina (FNIH) [T]

Subject: Friday's FNIH Board meeting

Good morning Francis. We got confirmation from Ayana that you have been able to move your calendar to attend the FNIH Board meeting on Friday, albeit for a short window. Thank you very, very much!

You will follow Anne Schuchat, acting Director of the CDC. She will give us an overview of the epidemic and brief us on the report they have just issued. We will send a final agenda a bit later today.

Since you have to leave soon after your presentation, we would be pleased if Larry and/or Carrie would like to join you and stay for the general discussion, which should last until 11:30am.

Larry, Carrie please consider this invitation; it would be good to have your input as the discussion progresses. Please let me you if you need a formal invitation letter.

Again, thank you for coming, Maria

**Sent:** Wed, 28 Feb 2018 11:19:58 +0000 **To:** Fennington, Kelly (NIH/OD) [E]

Cc: Baden, Elizabeth (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Collins, Francis

(NIH/OD) [E]; Klock, Kevin (FNIH) [T]; Wholley, David (FNIH) [T]

Subject: Fwd: Invitation to NIH ACD Meeting March 8

Kelly,

To clarify my reply - I will be flying most of the day on the 8th, arriving in DC the afternoon, too late to be able to get to the meeting on time. The 9th is fine. I hope that will work.

Best, Maria

## Begin forwarded message:

From: "Freire, Maria (FNIH) [T]" < mfreire@fnih.org>

Date: February 27, 2018 at 7:14:50 PM GMT-5

To: "Collins, Francis (NIH/OD) [E]" (b) (6)

Cc: "Wolinetz, Carrie (NIH/OD) [E]" (b) (6) "Fennington, Kelly

(NIH/OD) [E]" (b) (6), "Baden, Elizabeth (NIH/OD) [E]"

(b) (6), "Wholley, David (FNIH) [T]" < dwholley@fnih.org>, "Klock,

Kevin (FNIH) [T]" <kklock@fnih.org>

Subject: Re: Invitation to NIH ACD Meeting March 8

Hi Francis.

Thank you very much for the invitation. As I mentioned to your staff, I arrive in DC on the 8th. I will be pleased to join you on the 9th, however.

It would be very good to have David and Kevin there on the 8th and 9th. Is that possible? Best, Maria

On Feb 27, 2018, at 7:10 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear Maria,

I am writing to invite you to speak with the Advisory Committee to the NIH Director's Working Group on Ethical Considerations for Industry Partnership on Research to Help End the Opioid Crisis. The group is considering the appropriate ethical boundaries for engaging with and accepting resources from opioid producers in support of research to redress the opioid crisis.

As I know you are aware, for several months, NIH has been engaged with FNIH and potential external partners to identify and outline options for collaboration to address the opioid crisis. Discussions have included dozens of companies, a few of which manufacture opioids. While there may be significant opportunity to advance addiction and treatment research with the financial, technical, and intellectual

support of this substantial roster of private sector companies, one must consider the ethics of accepting contributions from those companies that are perceived as having contributed to the crisis.

To this end, the aforementioned working group is meeting in person to discuss these issues on March 8-9, 2018, on the NIH campus in Bethesda, Maryland. To inform their deliberations, the working group would like to hear from you, as the President and Executive Director of FNIH, to give your perspective on this potential partnership. I hope you will be able to join the meeting either in person or via teleconference/videoconference to address the group and share your insights.

I realize that this is short notice, but given the urgency of the current public health crisis, I am asking you to make this request a priority. If you are willing and able to accept the invitation, please respond to Kelly Fennington, Chief of Staff, Office of Science Policy

(b) (6) and we will follow up with additional information.

Thank you for considering this invitation and I hope you will accept.

Sincerely,

Francis

From: Freire, Maria (FNIH) [T] Sent: Thu, 1 Feb 2018 01:55:39 +0000 To: Collins, Francis (NIH/OD) [E] Fwd: Opioids RFC Subject: **FYI** Begin forwarded message: From: "Freire, Maria (FNIH) [T]" < mfreire@fnih.org> Date: January 29, 2018 at 4:24:46 PM EST To: "Baden, Elizabeth (NIH/OD) [E]" (b) (6) Cc: "Klock, Kevin (FNIH) [T]" < kklock@fnih.org >, "Wolf-Rodda, Julie (FNIH) [T]" < jwolfrodda@fnih.org>, "Wholley, David (FNIH) [T]" <dwholley@fnih.org> Subject: Re: Opioids RFC (b) (5) Elizabeth, (b) (5) (b) (5) Maria (b) (6) On Jan 29, 2018, at 4:14 PM, Baden, Elizabeth (NIH/OD) [E] wrote: Hi Maria, I appreciate FNIH's extraordinary efforts through the Development Phase of the Opioids (b) (5) program, (b)(5)

| (b) (5)                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Please feel free to give me a call if you would like to discuss any of this. I'm teleworking today, but you can reach me at the office tomorrow if you want to call then (b) (6).                                                                                                                   |
| Best,<br>Elizabeth                                                                                                                                                                                                                                                                                  |
| Original Message From: Freire, Maria (FNIH) [T] Sent: Monday, January 29, 2018 11:07 AM To: Baden, Elizabeth (NIH/OD) [E] Cc: Klock, Kevin (FNIH) [T] < kklock@fnih.org>; Wolf-Rodda, Julie (FNIH) [T] < jwolf-rodda@fnih.org>; Wholley, David (FNIH) [T] < dwholley@fnih.org> Subject: Opioids RFC |
| Good morning Elizabeth. We have not yet received the final RFC for the Development Phase of the Opioids program.  (b) (5)                                                                                                                                                                           |
| <b>(b)</b> (5)                                                                                                                                                                                                                                                                                      |
|                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                                                                                                                                                                                     |
| (b) (5)<br>Rest Maria                                                                                                                                                                                                                                                                               |

**Sent:** Wed, 14 Feb 2018 11:22:39 +0000

To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie

(NIH/OD) [E]; Wholley, David (FNIH) [T]

Cc: Klock, Kevin (FNIH) [T]

Subject: FYI

Interesting article. M.

 $\underline{https://www.theguardian.com/us-news/2018/feb/13/meet-the-sacklers-the-family-feuding-over-blame-for-the-opioid-crisis}$ 

**Sent:** Sat, 17 Mar 2018 11:59:39 +0000

To: Burklow, John (NIH/OD) [E];Collins, Francis (NIH/OD) [E];Tabak, Lawrence

(NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; McGarey, Barbara (NIH/OD) [E]

Subject: FYI

https://mobile.nytimes.com/2018/03/17/health/nih-alcohol-study-liquor-industry.html?referer=https://www.google.com/

**Sent:** Fri, 2 Mar 2018 13:54:48 +0000 **To:** Collins, Francis (NIH/OD) [E]

Cc: Tabak, Lawrence (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E];Steve Paul;Wholley, David (FNIH) [T];Klock, Kevin (FNIH) [T];Gonzalez-Cos, Francisco (FNIH) [T];Sepulveda, Dorina (FNIH) [T]

Subject: Invitation to the extraordinary FNIH Board of Directors Meeting

Importance: High

Dear Francis,

We received a letter from Dr. Lawrence Tabak requesting that the Board of Directors of the Foundation for the NIH (FNIH) consider a research partnership to help address opioid addiction and overdose and to develop non-addictive, effective pain medications. The FNIH is very well positioned to marshal the intellectual, technical and financial resources for this public-private partnership (PPP) and would like to contribute to the solution.

Dr. Tabak highlights that several companies that produce, market or distribute opioid medications have expressed a strong interest in contributing to the PPP and he rightfully notes the controversy that surrounds these companies and the role they may have played in the current opioid epidemic. Dr. Tabak asserts that, under certain circumstances, NIH believes that it could be appropriate for these companies to play a role in funding the PPP.

As you can appreciate, while it is critical that this public health emergency be addressed, it is essential that the FNIH efforts be beyond reproach. The patients and the public deserve this.

To that end, the FNIH has called an extraordinary Board of Directors meeting on March 16, 2018 at 9:00am at the FNIH offices at 11400 Rockville Pike, Suite 600, North Bethesda, Maryland. The meeting will allow the Directors to engage in a discussion with stakeholders to evaluate the ethical, reputational and other considerations that the Board believes must be weighed as part of a deliberative process to determine under what circumstances, if any, the FNIH could consider receiving funds from companies that produce, market or distribute opioid medications.

It is extremely important that the FNIH Board of Directors hear from you on this matter. **We would be honored if you could attend the meeting and make a short presentation** on the partnership so that the Board can understand its public health aims, financing considerations and governance. We anticipate the full discussion with you and other guests taking place from 9:00-11:30am. After that, the Board will meet in execution session to determine a course of action.

The FNIH is grateful for your leadership on this issue and your keen desire to see all Americans who suffer from pain or addition to be afforded the opportunity to live healthy lives. I apologize for the short notice but we want to get this done promptly.

With best regards, Maria

Maria C. Freire, Ph.D.
President and Executive Director

# Foundation for the National Institutes of Health

(301) 443-1811

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

2017 Gold Stevie Award Winner for Organization of the Year

**Sent:** Mon, 26 Mar 2018 20:57:24 +0000

To: Collins, Francis (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E];McManus, Ayanna (NIH/OD) [E];Meltzer, Abbey

(FNIH) [T];Balthaser, Robert (FNIH) [T]

Subject: Lurie Prize and Board Meeting

Attachments: Collins invitation.pdf

Dear Francis,

I hope you can join us again this year at the FNIH Award Ceremony to interview the Lurie Prize winner. He is terrific and has had NIH funding for 20 years! And, of course, we won't push for guitars but they are welcome.

All the best, Maria



March 26, 2018

Francis S. Collins, M.D., Ph.D. Director National Institutes of Health 1 Center Drive, Room 126 Bethesda, MD 20892-0148

Dear Dy. Col

The next FNIH Board of Directors meeting will take place on Thursday, May 17, 2018 from 8:00am – 2:00pm at our new offices located at 11400 Rockville Pike Suite, 600 North Bethesda, MD. As is customary, we welcome your participation and hope that you are amenable to making a brief presentation to the Board. We will be happy to find a time that best suits your schedule, should you be able to join us.

We are also delighted to invite you to participate at the FNIH Award Ceremony, which will take place the evening before on May 16, 2018 at the Organization of American States in Washington, D.C. I hope you will be able to attend again this year and be part of the celebration.

At the Award Ceremony, we will present the sixth Lurie Prize in Biomedical Sciences. As you know, the recipient this year is Dr. Zhijian "James" Chen, whose discovery of the enzyme cyclic GMP-AMP synthase (cGAS) and its corresponding pathway. Dr. Chen discovered the cellular process that uses DNA to activate the body's immune response to fight infections, in addition to its ability to inflict autoimmune disease. The Lurie Prize has become very well respected and coveted – a remarkable accomplishment given its short lifespan.

The highlight of the FNIH Award Ceremony is an engaging interview with the Lurie Prize recipient. Last year, you captivated the audience with insight into the work of Dr. Sabatini. It would be wonderful to have you conduct this portion of the program once again. Your presence and ability to communicate science will enthrall the audience in ways that will make Dr. Chen's research and the evening very exciting.

I hope you are able to attend both the FNIH Award Ceremony and the Board meeting. Your presence is always galvanizing.

With warm regards,

Maria C. Freire, Ph.D.

President and Executive Director

We love for your of hit!

**Sent:** Mon, 12 Feb 2018 15:33:51 +0000

To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie

(NIH/OD) [E]

Cc: Wholley, David (FNIH) [T];Burklow, John (NIH/OD) [E]

Subject: NYTimes story on PhRMA support for anti-addiction group

Francis, Larry, Carrie — I am sure you may have seen this article in the <u>New York Times</u> last week. Interesting to see the pushback the anti-addiction group is receiving after accepting contributions from PhRMA. M.

**Sent:** Wed, 21 Mar 2018 19:44:11 +0000

To: Collins, Francis (NIH/OD) [E]
Subject: RE: AMP OD - Nice editorial

Indeed. BTW, the NYT reporter that wrote the alcohol piece just called us about your remarks yesterday on the opioid PPP.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, March 21, 2018 3:43 PM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>; Tabak, Lawrence (NIH/OD) [E]

(b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)

Cc: Burklow, John (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>

Subject: RE: AMP OD - Nice editorial

Nice to see a positive press piece!

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, March 21, 2018 10:22 AM

To: Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]

(b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)

Cc: Burklow, John (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] < dwholley@fnih.org>

Subject: AMP OD - Nice editorial

Francis – in case you did not see The Lancet editorial. Yay!!! M.

From: Freire, Maria (FNIH) [T] Sent: Fri, 2 Feb 2018 19:36:43 +0000 Wolinetz, Carrie (NIH/OD) [E] To: Cc: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wholley, David (FNIH) [T]; Baden, Elizabeth (NIH/OD) [E] Subject: RE: Budget for the design phase of the opioids project Thank you Carrie. I will ask David to provide you (b) (5) Best, Maria From: Wolinetz, Carrie (NIH/OD) [E] Sent: Friday, February 2, 2018 2:28 PM To: Freire, Maria (FNIH) [T] <mfreire@fnih.org> Cc: Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baden, Elizabeth (NIH/OD) [E] Subject: Budget for the design phase of the opioids project Hi Maria. I wanted to follow up on the conversation about the budget for the design phase. (b) (5) (b)(5)

(b) (5) Cheers, Carrie

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health
(b) (6)

 Sent:
 Thu, 8 Feb 2018 17:31:04 +0000

 To:
 Wolinetz, Carrie (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wholley, David

(FNIH) [T]; Baden, Elizabeth (NIH/OD) [E]

Subject: RE: Budget for the design phase of the opioids project

Hi, Carrie. Per your request, here is the (b) (5) (b) (5) (b)(5)

From: Wolinetz, Carrie (NIH/OD) [E]
Sent: Friday, February 2, 2018 2:28 PM

| To: Freire, Maria (FNIH) [T] <mfreire< th=""><th>@fnih.org&gt;</th></mfreire<>           | @fnih.org>                                                                            |
|------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Cc: Collins, Francis (NIH/OD) [E]                                                        | (b) (6); Tabak, Lawrence (NIH/OD) [E]                                                 |
| (b) (6); Wholley                                                                         | , David (FNIH) [T] <dwholley@fnih.org>; Baden, Elizabeth (NIH/OD)</dwholley@fnih.org> |
| [E] (b) (6)                                                                              |                                                                                       |
| Subject: Budget for the design phase                                                     | e of the opioids project                                                              |
|                                                                                          |                                                                                       |
| Hi Maria,                                                                                |                                                                                       |
|                                                                                          |                                                                                       |
| I wanted to follow up on the conversation about the budget for the design phase. (b) (5) |                                                                                       |
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|                                                                                          |                                                                                       |
| (b) (                                                                                    | 5) Cheers, Carrie                                                                     |
| (6) (                                                                                    | Short, danie                                                                          |

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health
(b) (6)

NIH - 000765

**Sent:** Fri, 23 Feb 2018 19:40:45 +0000

To: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Collins, Francis

(NIH/OD) [E]

Subject: Re: EXTRAORDINARY BOARD MEETING - URGENT

Good grief, I accidentally sent this to my bother, not Francis. He must think I just landed from Mars. No harm done, M

On Feb 23, 2018, at 1:01 PM, Freire, Maria (FNIH) [T] <mfreire@fnih.org> wrote:

FYI, M.

From: Freire, Maria (FNIH) [T] Sent: Friday, February 23, 2018 12:50 PM To: 'Steve Paul' <steve@vygr.com>; (b) (6) Sol Snyder (ssnyder@jhmi.edu) <ssnyder@jhmi.edu>; 'Steve Mayer' (b) (6); 'Dame Jillian Sackler' (b) (6); 'Dr. Charles A. Sanders' (b) (6) >; 'Dr. Edison T. Liu' <Edison.Liu@jax.org>; esigal2 <esigal@focr.org>; Freda.Lewis-Hall <Freda.Lewis-Hall@pfizer.com>; 'Dr. Judy Lansing Kovler (b) (6); 'Dr. Kathy Bloomgarden' <bloomgardenk@ruderfinn.com>; Freire, Maria (FNIH) [T] <mfreire@fnih.org>; 'Dr. Martin J. Murphy' <marty@AMedConsulting.com>; 'Dr. Paul L. Herrling' (b) (6); 'Dr. Paul Montrone' <mchateauneuf@bayberryfinancial.com>; 'Dr. Paul Stoffels' <PStoffe4@its.jnj.com>; 'Dr. Ronald L. Krall' (b) (6); 'Dr. Samuel O. Thier' <sthier@partners.org>; 'Steven Paul - 2nd email' (b) (6); 'Dr. Thomas Insel' < tom@mindstronghealth.com >; 'Fred Seigel' <FSeigel@beaconcapital.com>; 'James H. Donovan' <james.donovan@gs.com>; 'Joel S. Marcus' (b) (6); 'Lily Safra' <mariaalba@earthlink.net>; 'Mrs. William (Buffy) N. Cafritz' (b) (6); 'Ms. Nina K. Solarz' (b) (6) >; 'Russell W. Steenberg' <russ.steenberg@blackrock.com> Cc: Wholley, David (FNIH) [T] < <a href="mailto:dwholley@fnih.org">dwholley@fnih.org</a>; Wolf-Rodda, Julie (FNIH) [T] < <a href="mailto:jwolf-rodd">jwolf-rodd</a>; Wolf-rodd</a>; Wolf-rodd (FNIH) [T] < <a href="mailto:jwolf-rodd">jwolf-rodd</a>; Wolf-rodd (FNIH) [T] < <a href="mailto:jwolf-rodd">jwolf-rodd</a>; Wolf-rodd (FNIH) [T] < <a href="mailto:jwolf-rodd">jwolf-rodd</a>; Wolf-rodd (FNIH rodda@fnih.org>; James, Stephanie (FNIH) [T] <sjames@fnih.org>; Klock, Kevin (FNIH) [T] <kklock@fnih.org>; Meltzer, Abbey (FNIH) [T] <ameltzer@fnih.org>; Hill, Donald (FNIH) [T] <dhill@fnih.org>; Gonzalez-Cos, Francisco (FNIH) [T] <fgonzalez-cos@fnih.org>; Balthaser, Robert (FNIH) [T] <rbalthaser@fnih.org>; Sepulveda, Dorina (FNIH) [T] <dsepulveda@fnih.org> Subject: EXTRAORDINARY BOARD MEETING CALL - URGENT

Dear Members of the Board of Directors,

Importance: High

NIH has expressed keen interest in having FNIH lead the Implementation Phase of the opioids project. Please see attached letter from Dr. Tabak, Deputy Director, NIH.

You may recall that for the initial phase of this project, FNIH worked closely with a number of stakeholders to develop a White Paper that provides the scientific blueprint for a potential Public Private Partnership. The two public health goals of the White Paper are to: 1) address overdosing and addition; and, 2) develop biomarkers that can lead to non-addictive pain therapies.

It is now time to move onto the Implementation Phase. We believe that the FNIH can play a very important role in addressing the opioids crisis and that it is uniquely positioned to do so.

Financially, the project requires \$250 million in government funds and \$250 million from non-government sources, over 5 years. The pharmaceutical industry's trade organization, PhRMA, is working to enlist its members to help support this partnership with up to \$250M in funding over 5 years. This includes support from companies that are involved in the opioid controversy.

FNIH is calling for an extraordinary Board meeting in mid-March, the date of which will be determined in the next few days after polling the Board members. The meeting will include external stakeholders (ethicists, patients, NIH, etc.), followed by an Executive Session.

The FNIH Board will be asked to consider the ethical, reputational and other risks involved in potentially accepting funding from companies that are associated with or are perceived to have contributed to the opioid epidemic in the United States.

The goal of this meeting is to fully discuss the pros and cons of the accepting the funds in question and to make a well-reasoned decision under what circumstances, if any, would FNIH receive such contributions.

You will be contacted immediately by Ms. Dorina Sepulveda to assess your availability.

Please note that Dame Jillian Sackler and Dr. Paul Stoffels, while on this distribution list as members of the FNIH Board of Directors, have recused themselves from these discussions.

Thank you, Maria

<Letter to Dr. Freire from Dr. Tabak Opioid Crisis.pdf>

**Sent:** Fri, 16 Feb 2018 23:56:32 +0000 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Follow-up to our dinner with Mark Burnett at Hay Adams

Absolutely, thank you! Send him my way, M.

On Feb 16, 2018, at 4:22 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Any interest in my linking you up with Knaster? It's fine to say no.

FC

From: bob.foresman@ubs.com [mailto:bob.foresman@ubs.com]

Sent: Friday, February 16, 2018 11:26 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Follow-up to our dinner with Mark Burnett at Hay Adams

Dear Francis,

It was a great pleasure being seated next to you at the wonderful dinner last Thursday evening at the Hay Adams, with our dear friends Mark Burnett and Roma Downey. I very much enjoyed our discussion, and very, VERY much enjoyed your beautiful guitar playing and singing, and joining you in what I hope was harmony!

You may recall that I asked you whether NIH sometimes partners with private philanthropy, and you confirmed that indeed you do. I mentioned Alex Knaster, an extraordinary NY-based private equity firm owner, billionaire, and leader in cancer research. You will find a link to his Wikipedia page and his Mark Foundation, below.

I told Alex about you and he would love to meet you at your convenience. Can I connect you? I highly, highly recommend it.

Blessings,

Bob Foresman

https://en.wikipedia.org/wiki/Alexander Knaster

https://themarkfoundation.org/

<disclaim.txt>

**Sent:** Fri, 16 Mar 2018 07:30:32 +0000 **To:** Tabak, Lawrence (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E];Klock, Kevin (FNIH) [T];Sepulveda, Dorina (FNIH)

[T];Gonzalez-Cos, Francisco (FNIH) [T]

Subject: Re: Friday's FNIH Board meeting

Larry, we would be absolutely honored if you could attend! I just got the response from Carrie but not from you. Thank for making the time; it would be terrific and much appreciated. We will fix the list first thing, M

```
> On Mar 15, 2018, at 11:03 PM, Tabak, Lawrence (NIH/OD) [E]

**Maria*,

* I note that I am not listed as a guest tomorrow; please let me know if you prefer that I not attend.

* larry

* Son 3/13/18, 8:42 AM, "Freire, Maria (FNIH) [T]" < mfreire@fnih.org> wrote:

* Good morning Francis. We got confirmation from Ayana that you have been able to move your calendar to
```

- attend the FNIH Board meeting on Friday, albeit for a short window. Thank you very, very much!
- > You will follow Anne Schuchat, acting Director of the CDC. She will give us an overview of the epidemic and brief us on the report they have just issued. We will send a final agenda a bit later today.
- > Since you have to leave soon after your presentation, we would be pleased if Larry and/or Carrie would like to join you and stay for the general discussion, which should last until 11:30am.
- > Larry, Carrie please consider this invitation; it would be good to have your input as the discussion progresses. Please let me you if you need a formal invitation letter.
- > Again, thank you for coming, Maria

Sent: Fri, 16 Mar 2018 10:02:07 +0000

To: Tabak, Lawrence (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E]

Subject: Re: Friday's FNIH Board meeting

Larry, Steve Paul was very happy to hear you would be coming. Thanks again, M.

```
> On Mar 15, 2018, at 11:03 PM, Tabak, Lawrence (NIH/OD) [E]

> Maria,
> I note that I am not listed as a guest tomorrow; please let me know if you prefer that I not attend.
> larry
>
> --
> On 3/13/18, 8:42 AM, "Freire, Maria (FNIH) [T]" <mfreire@fnih.org> wrote:
>
```

- > Good morning Francis. We got confirmation from Ayana that you have been able to move your calendar to attend the FNIH Board meeting on Friday, albeit for a short window. Thank you very, very much!
- > You will follow Anne Schuchat, acting Director of the CDC. She will give us an overview of the epidemic and brief us on the report they have just issued. We will send a final agenda a bit later today.
- > Since you have to leave soon after your presentation, we would be pleased if Larry and/or Carrie would like to join you and stay for the general discussion, which should last until 11:30am.
- > Larry, Carrie please consider this invitation; it would be good to have your input as the discussion progresses. Please let me you if you need a formal invitation letter.
- > Again, thank you for coming, Maria >

**Sent:** Wed, 28 Feb 2018 12:11:43 +0000 **To:** Fennington, Kelly (NIH/OD) [E]

Cc: Baden, Elizabeth (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Collins, Francis

(NIH/OD) [E];Klock, Kevin (FNIH) [T];Wholley, David (FNIH) [T]

Subject: Re: Invitation to NIH ACD Meeting March 8

Thanks Kelly. It would be good if Kevin and David could attend Day 1 so I can get the context. Best, M.

On Feb 28, 2018, at 7:03 AM, Fennington, Kelly (NIH/OD) [E] (b) (6) wrote:

Hi Maria,

Thanks for clarifying and this works well on our end. We will add you to the agenda on March 9 and send you meeting materials as soon as we can. Many thanks for your participation.

## Kelly

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, February 28, 2018 6:20 AM

To: Fennington, Kelly (NIH/OD) [E] (b) (6)

Cc: Baden, Elizabeth (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]

(b) (6) Collins, Francis (NIH/OD) [E] (b) (6) Klock, Kevin (FNIH) [T]

<kklock@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>

Subject: Fwd: Invitation to NIH ACD Meeting March 8

Kelly,

To clarify my reply - I will be flying most of the day on the 8th, arriving in DC the afternoon, too late to be able to get to the meeting on time. The 9th is fine. I hope that will work.

Best, Maria

### Begin forwarded message:

From: "Freire, Maria (FNIH) [T]" < mfreire@fnih.org>

Date: February 27, 2018 at 7:14:50 PM GMT-5

To: "Collins, Francis (NIH/OD) [E]" (b) (6)

Cc: "Wolinetz, Carrie (NIH/OD) [E]" (b) (6), "Fennington, Kelly (NIH/OD) [E]"

(b) (6) >, "Baden, Elizabeth (NIH/OD) [E]" (b) (6), "Wholley, David

(FNIH) [T]" <dwholley@fnih.org>, "Klock, Kevin (FNIH) [T]" <kklock@fnih.org>

Subject: Re: Invitation to NIH ACD Meeting March 8

Hi Francis.

Thank you very much for the invitation. As I mentioned to your staff, I arrive in DC on the 8th. I will be pleased to join you on the 9th, however.

It would be very good to have David and Kevin there on the 8th and 9th. Is that possible?

Best, Maria

On Feb 27, 2018, at 7:10 PM, Collins, Francis (NIH/OD) [E] (b) (6) > wrote:

Dear Maria,

I am writing to invite you to speak with the Advisory Committee to the NIH Director's Working Group on Ethical Considerations for Industry Partnership on Research to Help End the Opioid Crisis. The group is considering the appropriate ethical boundaries for engaging with and accepting resources from opioid producers in support of research to redress the opioid crisis.

As I know you are aware, for several months, NIH has been engaged with FNIH and potential external partners to identify and outline options for collaboration to address the opioid crisis. Discussions have included dozens of companies, a few of which manufacture opioids. While there may be significant opportunity to advance addiction and treatment research with the financial, technical, and intellectual support of this substantial roster of private sector companies, one must consider the ethics of accepting contributions from those companies that are perceived as having contributed to the crisis.

To this end, the aforementioned working group is meeting in person to discuss these issues on March 8-9, 2018, on the NIH campus in Bethesda, Maryland. To inform their deliberations, the working group would like to hear from you, as the President and Executive Director of FNIH, to give your perspective on this potential partnership. I hope you will be able to join the meeting either in person or via teleconference/videoconference to address the group and share your insights.

I realize that this is short notice, but given the urgency of the current public health crisis, I am asking you to make this request a priority. If you are willing and able to accept the invitation, please respond to Kelly Fennington, Chief of Staff, Office of Science Policy

(b) (6), and we will follow up with additional information.

Thank you for considering this invitation and I hope you will accept. Sincerely,

Francis

**Sent:** Wed, 28 Feb 2018 00:14:50 +0000 **To:** Collins, Francis (NIH/OD) [E]

Cc: Wolinetz, Carrie (NIH/OD) [E]; Fennington, Kelly (NIH/OD) [E]; Baden, Elizabeth

(NIH/OD) [E]; Wholley, David (FNIH) [T]; Klock, Kevin (FNIH) [T] **Subject:** Re: Invitation to NIH ACD Meeting March 8

Hi Francis.

Thank you very much for the invitation. As I mentioned to your staff, I arrive in DC on the 8th. I will be pleased to join you on the 9th, however.

It would be very good to have David and Kevin there on the 8th and 9th. Is that possible?

Best, Maria

On Feb 27, 2018, at 7:10 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

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As I know you are aware, for several months, NIH has been engaged with FNIH and potential external partners to identify and outline options for collaboration to address the opioid crisis. Discussions have included dozens of companies, a few of which manufacture opioids. While there may be significant opportunity to advance addiction and treatment research with the financial, technical, and intellectual support of this substantial roster of private sector companies, one must consider the ethics of accepting contributions from those companies that are perceived as having contributed to the crisis.

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I realize that this is short notice, but given the urgency of the current public health crisis, I am asking you to make this request a priority. If you are willing and able to accept the invitation, please respond to Kelly Fennington, Chief of Staff, Office of Science Policy

(b) (6), and we will follow up with additional information.

Thank you for considering this invitation and I hope you will accept.

Sincerely,

Francis

**Sent:** Wed, 28 Feb 2018 13:31:30 +0000 **To:** Wolinetz, Carrie (NIH/OD) [E]

Cc: Fennington, Kelly (NIH/OD) [E];Baden, Elizabeth (NIH/OD) [E];Collins, Francis

(NIH/OD) [E];Klock, Kevin (FNIH) [T];Wholley, David (FNIH) [T] **Subject:** Re: Invitation to NIH ACD Meeting March 8

Hi Carrie, thank you - that makes sense. Please let me know who will be in the room when I present. May I bring Kevin and/or David then? Best, M.

On Feb 28, 2018, at 7:51 AM, Wolinetz, Carrie (NIH/OD) [E] (b) (6) wrote:

Hi Maria.

Our Working Group meetings are typically closed sessions, to allow for candid discussion. Presenters come only for their portion of the discussion. Cheers, Carrie Carrie D. Wolinetz, Ph.D.

Acting Chief of Staff and

Associate Director for Science Policy

Office of the Director

National Institutes of Health

301-496-2122

----- Original message -----

From: "Freire, Maria (FNIH) [T]" <mfreire@fnih.org>

Date: 2/28/18 7:11 AM (GMT-05:00)

To: "Fennington, Kelly (NIH/OD) [E]" (b) (6) >

Cc: "Baden, Elizabeth (NIH/OD) [E]" (b) (6) >, "Wolinetz, Carrie (NIH/OD)

(b) (6) >

[E]" (b) (6), "Collins, Francis (NIH/OD) [E]"

"Klock, Kevin (FNIH) [T]" < kklock@fnih.org>, "Wholley, David (FNIH) [T]"

<dwholley@fnih.org>

Subject: Re: Invitation to NIH ACD Meeting March 8

Thanks Kelly. It would be good if Kevin and David could attend Day 1 so I can get the context.

Best, M.

On Feb 28, 2018, at 7:03 AM, Fennington, Kelly (NIH/OD) [E] (b) (6) wrote:

Hi Maria,

Thanks for clarifying and this works well on our end. We will add you to the agenda on March 9 and send you meeting materials as soon as we can. Many thanks for your participation.

Kelly

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, February 28, 2018 6:20 AM

(b)(6)To: Fennington, Kelly (NIH/OD) [E] Cc: Baden, Elizabeth (NIH/OD) [E] (b) (6) >; Wolinetz, Carrie (NIH/OD) [E] (b) (6); Klock, Kevin (FNIH) [T] (b) (6); Collins, Francis (NIH/OD) [E] <kklock@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org> Subject: Fwd: Invitation to NIH ACD Meeting March 8 Kelly, To clarify my reply - I will be flying most of the day on the 8th, arriving in DC the afternoon, too late to be able to get to the meeting on time. The 9th is fine. I hope that will work. Best, Maria Begin forwarded message: From: "Freire, Maria (FNIH) [T]" < mfreire@fnih.org> Date: February 27, 2018 at 7:14:50 PM GMT-5 To: "Collins, Francis (NIH/OD) [E]" (b)(6)(b) (6), "Fennington, Kelly (NIH/OD) [E]" Cc: "Wolinetz, Carrie (NIH/OD) [E]" (b) (6) "Baden, Elizabeth (NIH/OD) [E]" (b) (6) >, "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Klock, Kevin (FNIH) [T]" <kklock@fnih.org> Subject: Re: Invitation to NIH ACD Meeting March 8 Hi Francis. Thank you very much for the invitation. As I mentioned to your staff, I arrive in DC on the 8th. I will be pleased to join you on the 9th, however. It would be very good to have David and Kevin there on the 8th and 9th. Is that possible?

Best, Maria

On Feb 27, 2018, at 7:10 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear Maria,

I am writing to invite you to speak with the Advisory Committee to the NIH Director's Working Group on Ethical Considerations for Industry Partnership on Research to Help End the Opioid Crisis. The group is considering the appropriate ethical boundaries for engaging with and accepting resources from opioid producers in support of research to redress the opioid crisis.

As I know you are aware, for several months, NIH has been engaged with FNIH and potential external partners to identify and outline options for collaboration to address the opioid crisis. Discussions have included dozens of companies, a few of which manufacture opioids. While there may be significant opportunity to advance addiction and treatment research with the financial, technical, and intellectual support of this substantial roster of private sector companies, one must consider the ethics of accepting contributions from those companies that are perceived as having contributed to the crisis.

To this end, the aforementioned working group is meeting in person to discuss these issues on March 8-9, 2018, on the NIH campus in Bethesda, Maryland. To inform their deliberations, the working group would like to hear from you, as the President and Executive Director of FNIH, to give your perspective on this potential partnership. I hope you will be able to join the meeting either in person or via teleconference/videoconference to address the group and share your insights.

I realize that this is short notice, but given the urgency of the current public health crisis, I am asking you to make this request a priority. If you are willing and able to accept the invitation, please respond to Kelly Fennington, Chief of Staff, Office of Science Policy

(b) (6) and we will follow up with additional information.

Thank you for considering this invitation and I hope you will accept. Sincerely, Francis

**Sent:** Fri, 6 Apr 2018 15:56:35 +0000

To: Dr. Martin J. Murphy, Jr.; Dr. Steven M. Paul (steve@voyagertherapeutics.com)

Cc: Dr. Solomon H. Snyder (ssnyder@jhmi.edu); Dr. Charles A. Sanders

(b) (6);Collins, Francis (NIH/OD) [E];Klock, Kevin (FNIH) [T] RE: Martin Murphy - Board Term Renewal Request

Dear Marty,

Subject:

While your decision not to stand for reelection is understandable after having given FNIH 12 outstanding years of service, you will forgive us for being disappointed. We will miss your insight and wisdom and, of course, your marvelous way of turning a phrase, which is the envy of us all.

Thank you especially for your leadership in the Charles Sanders Legacy Fund and for the many, many scientific and strategic discussions to which you have greatly contributed during your tenure. It is comforting to know that we will still be connected via Project Data Sphere and perhaps other novel initiatives in the future.

We hope to see you for the Award dinner and Board meeting in May!

With sincere appreciation and all good wishes, always, Maria

From: Dr. Martin J. Murphy, Jr. [mailto:martin.murphy@ceoroundtableoncancer.org]

Sent: Friday, April 6, 2018 9:43 AM

To: Dr. Steven M. Paul (steve@voyagertherapeutics.com) < steve@voyagertherapeutics.com>; Freire,

Maria (FNIH) [T] <mfreire@fnih.org>

Cc: Dr. Solomon H. Snyder (ssnyder@jhmi.edu) <ssnyder@jhmi.edu>; Dr. Charles A. Sanders

(b) (6); Collins, Francis (NIH/OD) [E]

(b) (6)

Subject: Martin Murphy - Board Term Renewal Request

Dear Steve and Maria,

"Revelation" is known to hide within guises ... challenging a perceptive spirit to decipher its true meaning.

It has been revealed to me that now is the time to reduce my commitments.

In tendering my decision not to stand for re-election to the *FNIH Board of Directors*, I take my leave fulfilled in the knowledge that the Foundation is secure in its leaders and, therefore, in its future.

I shall take with me the warmth of friends who have honored me with trust and who have showered Ann and me with kindnesses.

To one and all, I share only my

# Choicest regards,

# Marty

Martin J. Murphy, DMedSc, PhD, FASCO Chief Executive Officer CEO Roundtable on Cancer

P: +919.402.8750 (office)
C: (b) (6) (cell)
F: +919.402.9799 (fax)

E: Martin.Murphy@CEORoundtableOnCancer.org



www.CEORoundtableOnCancer.org www.CancerGoldStandard.org www.CEO-LSC.org www.ProjectDataSphere.org

From: Freire, Maria (FNIH) [T] [mailto:mfreire@fnih.org]

Sent: Friday, April 06, 2018 4:40 AM

**To:** Dr. Martin J. Murphy, Jr. **Subject:** Renewal request

Dear Marty,

On behalf of the Governance Committee, please find the attached letter requesting that you consider extending your tenure as a member of the Board at the FNIH. Knowing how busy you are, I know this is an big imposition but I hope you will consider this positively.

All the best, Maria

**Sent:** Sun, 14 Jan 2018 23:17:25 +0000 **To:** Collins, Francis (NIH/OD) [E]

Cc: Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Hallett, Adrienne

(NIH/OD) [E];Burklow, John (NIH/OD) [E];Wood, Gretchen (NIH/OD) [E];Bloomfield Jones, Sandra

(NIH/OD) [E]

Subject: Re: Not going to Abu Dhabi

Wise decision, Francis.

On Jan 14, 2018, at 6:01 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Benefits not judged to be worth the trip.

FC

**Sent:** Sun, 18 Mar 2018 18:53:53 +0000 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: opioids PPP

Hi Francis. Any chance we could talk by phone or I could buy you a coffee? M.

On Mar 18, 2018, at 1:42 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Hi Maria,

I suspect you are as distracted as I am by today's NYT. Ugh.

But meanwhile, I'm intensely curious to know about the outcome of the FNIH Board Executive Session on Friday. I don't want to push this inappropriately, but what is the plan for sharing the sense of the Board with Larry, Carrie, and me?

Best, Francis

**Sent:** Sun, 18 Mar 2018 19:47:24 +0000 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: opioids PPP

Sounds good. My cell is easiest - (b) (6).

On Mar 18, 2018, at 3:46 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Drowning today and this evening – but how about a call tomorrow around 8:15 AM?

FC

From: Freire, Maria (FNIH) [T]

Sent: Sunday, March 18, 2018 2:54 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Re: opioids PPP

Hi Francis. Any chance we could talk by phone or I could buy you a coffee?

M.

On Mar 18, 2018, at 1:42 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Hi Maria,

I suspect you are as distracted as I am by today's NYT. Ugh.

But meanwhile, I'm intensely curious to know about the outcome of the FNIH Board Executive Session on Friday. I don't want to push this inappropriately, but what is the plan for sharing the sense of the Board with Larry, Carrie, and me?

Best, Francis

**Sent:** Tue, 20 Feb 2018 19:54:09 +0000 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Ready to go

(b) (6)

Thanks so much, M.

On Feb 20, 2018, at 2:51 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Working on it, (b) (6), should have something soon...

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, February 20, 2018 7:35 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Ready to go

Francis, we have the email calling for a extraordinary Board meeting at the ready. Could you push a bit on the NIH letter so we can send out the notice? Thanks, M.

 Sent:
 Tue, 20 Feb 2018 12:34:58 +0000

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Ready to go

Francis, we have the email calling for a extraordinary Board meeting at the ready. Could you push a bit on the NIH letter so we can send out the notice? Thanks, M.

**Sent:** Tue, 20 Mar 2018 15:03:50 +0000 **To:** Tabak, Lawrence (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Steve Paul; Klock,

Kevin (FNIH) [T]

Subject: Response to Dr. Tabak's letter of 2/23/18
Attachments: 20Mar18 FNIH-Dr. Tabak Letter.pdf

Dear Larry,

Enclosed please find the letter responding to your inquiry of February 23<sup>rd</sup>. Please let me know if you have any questions.

Best regards, Maria





 Sent:
 Tue, 23 Jan 2018 15:45:52 +0000

 To:
 Tabak, Lawrence (NIH/OD) [E]

 Cc:
 Collins, Francis (NIH/OD) [E]

Subject: Trailblazer Prize for Clinician Scientists

Good morning Larry. It is good to have you back in business!

This morning the FNIH announced a new award for early-career clinician scientists – the Trailblazer Prize.

Here is the press release: <a href="https://fnih.org/news/press-releases/foundation-nih-opens-nominations-inaugural-trailblazer-prize-clinician-scientists">https://fnih.org/what-we-do/current-lectures-awards-and-events/trailblazer-prize</a>.

We would be very appreciative if this Prize and the Lurie Prize could go through the NIH review that would allow NIH staff to receive it. We are certain there are some very meritorious NIH scientists and clinician-scientists that would come to the top if nominated.

Given that I had to review these while at ACD, I know there is a procedure to follow. Who should be our contact person?

Many thanks, Maria

**Sent:** Sun, 4 Mar 2018 13:45:51 +0000

To: Collins, Francis (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence

(NIH/OD) [E]

Cc: Wholley, David (FNIH) [T]; Klock, Kevin (FNIH) [T]

Subject: When Should Cultural Institutions Say No to Tainted Funding? - The New York

Times

FYI.

 $\underline{https://www.nytimes.com/2018/03/02/nyregion/when-should-cultural-institutions-say-no-to-tainted-funding.html}$ 

**Sent:** Tue, 18 Jun 2013 15:41:15 -0400

To: Herrling, Paul (paul.herrling@novartis.com)

Cc: Collins, Francis (NIH/OD) [E]

Subject: Brain

Dear Paul,

I've followed up with Francis (copied here) regarding your suggestion that the two of you compare notes on the US and EU initiatives on the brain. He welcomes your offer and is keen to get your perspective. Perhaps the best way would be for the two of you to connect directly on a phone call? As always, all the best, Maria

 Sent:
 Thu, 3 Oct 2013 11:20:36 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 White, Pat (NIH/OD) [E]

Subject: Re: Klobuchar donates salary to FNIH

Francis, we have no record of any call, e-mail or letter about this, except the tweet. I'll circle back with Pat White, copied here, to see how we approach her. It would be nice to get some traction here. M.

---- Original Message -----

From: Collins, Francis (NIH/OD) [E] Sent: Thursday, October 03, 2013 10:32 AM

To: Freire, Maria (FNIH) [T]

Subject: FW: Klobuchar donates salary to FNIH

Did you already know about this?

----Original Message----

From: White, Pat (NIH/OD) [E]

Sent: Thursday, October 03, 2013 8:13 AM

To: Collins, Francis (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: Klobuchar donates salary to FNIH

Sen. Amy Klobuchar (D-Minn.): The senator "is giving her pay during the government shutdown to the Foundation for the National Institutes of Health, since lifesaving NIH medical research is being slashed during the shutdown," a spokeswoman said in an e-mail.

 Sent:
 Thu, 2 May 2013 14:02:48 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: RE: Senate dashes hopes for travel to Chicago

Hi, Francis. We are eagerly awaiting your video for the Lurie dinner – I know it will be just great! Eric Neilson has volunteered to say a few words so we should be fine speaker-wise (although he will be a pale reflection of you). However, you had offered to call in for a few minutes during the Board meeting the morning of the 15<sup>th</sup> – if the offer is still on, would 10am work for you? Maybe 20min or so? It would be great to get your perspective on Target Validation, BRAIN (Ernesto and I were laughing aloud with the Colbert interview, by the way), MRSP or, of course, on ANYTHING you may want to address.... If it turns out to be a crazy time, just let me know. See you on May 10<sup>th</sup> for our catch-up meeting. Best, M.

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, April 24, 2013 5:53 AM

To: (b) (6); egneilson@northwestern.edu

Cc: Freire, Maria (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: Senate dashes hopes for travel to Chicago

Dear Ann and Eric,

Following our prior conversations about the events in Chicago on May 14 - 15, I did major surgery on my calendar to attend the Lurie Prize dinner on the evening of May 14 and the FNIH Board meeting on the morning of May 15. But it seems the Senate had other plans.

The Senate Appropriations Subcommittee with jurisdiction over NIH (Harkin, chair) has now announced the FY14 NIH appropriation hearing will be held on the afternoon of May 15, with me as the main witness. As you know this is a critical step in what we hope will be a rescue of the seriously damaged NIH budget. There is no way I can get to the hearing if I am in Chicago that morning — and more than that, there are always a zillion last minute items that emerge the evening before a hearing (as Senators and their staff provide a heads up about what they may want to ask about, and deep dives into specific details have to be made). For the good of NIH, I just can't afford to be somewhere else that evening.

So with deep regret, I am going to have to withdraw from the plans to be in Chicago in person. I have just informed Maria of that unfortunate reality. I will be glad to send a video for the Lurie Prize event – and, if you like, I will even volunteer to conclude my video remarks with a song written for the occasion. If it would help, I could also call in for some part of the FNIH Board meeting.

I am very disappointed by this turn of events, as I am sure you are also -- but I hope everyone in Chicago will understand this is completely out of my hands.

With very best regards,

Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)
www.nih.gov/about/director

**Sent:** Thu, 2 May 2013 15:01:11 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen

(NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Payne, Laura (FNIH) [T]; Gray, Felicia (FNIH) [T]

Subject: RE: Senate dashes hopes for travel to Chicago

Fabulous! It is 10am your time (the meeting starts at 8:45am Chicago time). We will give Ayanna the call-in information as we get closer to the date. Thanks, Francis!

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, May 02, 2013 2:50 PM

To: Freire, Maria (FNIH) [T]

Cc: Hudson, Kathy (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E];

Burklow, John (NIH/OD) [E]

Subject: RE: Senate dashes hopes for travel to Chicago

Hi Maria,

Yes, I think I could call in for 20 minutes at 10 AM EDT (you did mean EDT, right?) on May 15. I'll think about what topics to include.

Best regards, Francis

From: Freire, Maria (FNIH) [T]
Sent: Thursday, May 02, 2013 2:03 PM
To: Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E]

Subject: RE: Senate dashes hopes for travel to Chicago

Hi, Francis. We are eagerly awaiting your video for the Lurie dinner – I know it will be just great! Eric Neilson has volunteered to say a few words so we should be fine speaker-wise (although he will be a pale reflection of you). However, you had offered to call in for a few minutes during the Board meeting the morning of the 15<sup>th</sup> – if the offer is still on, would 10am work for you? Maybe 20min or so? It would be great to get your perspective on Target Validation, BRAIN (Ernesto and I were laughing aloud with the Colbert interview, by the way), MRSP or, of course, on ANYTHING you may want to address.... If it turns out to be a crazy time, just let me know. See you on May 10<sup>th</sup> for our catch-up meeting. Best, M.

From: Collins, Francis (NIH/OD) [E] Sent: Wednesday, April 24, 2013 5:53 AM

To: (b) (6); egneilson@northwestern.edu

Cc: Freire, Maria (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

**Subject:** Senate dashes hopes for travel to Chicago

Dear Ann and Eric.

Following our prior conversations about the events in Chicago on May 14 - 15, I did major surgery on my calendar to attend the Lurie Prize dinner on the evening of May 14 and the FNIH Board meeting on the morning of May 15. But it seems the Senate had other plans.

The Senate Appropriations Subcommittee with jurisdiction over NIH (Harkin, chair) has now announced the FY14 NIH appropriation hearing will be held on the afternoon of May 15, with me as the main witness. As you know this is a critical step in what we hope will be a rescue of the seriously damaged NIH budget. There is no way I can get to the hearing if I am in Chicago that morning — and more than that, there are always a zillion last minute items that emerge the evening before a hearing (as Senators and their staff provide a heads up about what they may want to ask about, and deep dives into specific details have to be made). For the good of NIH, I just can't afford to be somewhere else that evening.

So with deep regret, I am going to have to withdraw from the plans to be in Chicago in person. I have just informed Maria of that unfortunate reality. I will be glad to send a video for the Lurie Prize event—and, if you like, I will even volunteer to conclude my video remarks with a song written for the occasion. If it would help, I could also call in for some part of the FNIH Board meeting.

I am very disappointed by this turn of events, as I am sure you are also -- but I hope everyone in Chicago will understand this is completely out of my hands.

With very best regards,

Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)
www.nih.gov/about/director

**Sent:** Thu, 3 Oct 2013 10:35:56 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Klobuchar donates salary to FNIH

Nope. I'll find out and get back to you.

---- Original Message -----

From: Collins, Francis (NIH/OD) [E] Sent: Thursday, October 03, 2013 10:32 AM

To: Freire, Maria (FNIH) [T]

Subject: FW: Klobuchar donates salary to FNIH

Did you already know about this?

----Original Message----

From: White, Pat (NIH/OD) [E]

Sent: Thursday, October 03, 2013 8:13 AM

To: Collins, Francis (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: Klobuchar donates salary to FNIH

Sen. Amy Klobuchar (D-Minn.): The senator "is giving her pay during the government shutdown to the Foundation for the National Institutes of Health, since lifesaving NIH medical research is being slashed during the shutdown," a spokeswoman said in an e-mail.

**Sent:** Mon, 24 Mar 2014 16:30:36 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; White, Pat (NIH/OD)

[E]

Subject: OSTP - FYI only

Francis, Kathy, Pat – OSTP (Doug Rand and Mike Stebbins) have asked for a FNIH 101 briefing to learn "more about how the FNIH functions with a particular eye to potentially trying to establish FNIH-like entities for other agencies (similar to the new FUSDA)." Imitation being the sincerest form of flattery, this makes us feel good and since we had a hand in standing FUSDA and the Reagan-Udall Foundation, we will, indeed, have something to say. I worry, however, that this cloning will soon make the field so crowded that it will render the model ineffective. I'll keep you posted. M.

**Sent:** Thu, 18 Sep 2014 12:22:20 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Gottesman, Michael (NIH/OD) [E];Wyatt, Richard G (NIH/OD) [E];Burklow, John

(NIH/OD) [E];Hudson, Kathy (NIH/OD) [E];Milgram, Sharon (NIH/OD) [E];Wolf-Rodda, Julie (FNIH)

[T]; Acland, Emily (FNIH) [T]

Subject: Very good news!

#### CONFIDENTIAL

#### Francis,

I am very pleased to let you know that last night we received word from the Amgen Foundation that they are awarding us a grant of \$850,000 over four years to establish an Amgen-NIH Scholars Program in the NIH Intramural Research Program. These funds will enhance OITE's existing summer internship program, supporting 20 college-age scholars each summer. As with the summer program overall, the goal to prepare a cadre of highly diverse students for graduate education, possessing the personal, professional and scientific skills to succeed in the highly collaborative and complex global research community. Applications will be accepted beginning in 2014 and scholars would first appear on the NIH campus next summer, in 2015.

NIH will be one of a network of 10 sites hosting Amgen Scholars in the U.S. and 7 sites internationally. Eight of the 10 current U.S. sites were renewed; two, including NIH, were added and two were dropped (the new list is not yet public). We are told that the international sites will include the Karolinska, ETH Zurich, Cambridge, Pasteur, Ludwig-Maximilians-Universität, University of Tokyo, and Kyoto Univ. With these grants, Amgen's investment in this program has reached \$50M. The program's website is <a href="http://www.amgenscholars.com/">http://www.amgenscholars.com/</a>

FNIH staff developed the proposal working closely with Sharon Milgram, Director of OITE; it has been a great collaboration and we are delighted it worked out positively.

Amgen plans a major public announcement in early November and will work with FNIH and NIH prepare for this announcement – John, we will make sure you are in the loop.

Onward and upward! Maria

 Sent:
 Tue, 23 Dec 2014 11:03:45 -0500

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: Lung Cancer Screening Challenge ("Coding For Cancer")

Francis, the Arnold Foundation just let us know that they are giving us a grant for \$2.4M to support this lung cancer screening challenge – onward and upward! I am letting you know because the WH has been interested in getting this done, as has Harold. Mike Stebbins was very helpful in introducing us to Stuart Buck at the Arnold Foundation, so kudos to him, to Paula Jacobs at NCI, who was absolutely terrific, and to the FNIH folks who have worked so hard on this. Great end to a very good FNIH year. Ho, Ho, Ho! M.

Sent: Wed, 4 Feb 2015 15:26:39 -0500

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E]
Subject: WSJ - Manhattan Institute - FYI

# THE WALL STREET JOURNAL.

# What Failed, the New Cancer Treatment or Regulators?

Feb 3, 2015 By Peter Huber And Paul Howard

Bureaucracy and outdated rules too often block potential breakthroughs, but now hope is on the horizon.

Washington's leaders rarely focus on how bureaucracy and outdated regulations handicap the efforts of America's most innovative companies and researchers to bring new treatments to patients. But it's happening.

Last week the 21st Century Cures initiative—spearheaded by House Energy and Commerce Chairman Fred Upton (R., Mich.) and Rep. Diana DeGette (D., Colo.)—released a report offering bipartisan suggestions for streamlining clinical trials and reforming the Food and Drug Administration's regulation of emerging technologies. Sens. Lamar Alexander (R., Tenn.) and Richard Burr (R., N.C.) issued their own call for reform, arguing that "too many patients with no treatment options wait while potential treatments languish in laboratories."

Their efforts won't founder for lack of evidence.

At the forefront of cancer treatment, rare responses to experimental drugs are helping rewrite the rules of drug development, rescuing seemingly failed medicines and saving lives along the way.

| The science behind these responses should lead to a broad rethinking of the FDA's clinical-trial |
|--------------------------------------------------------------------------------------------------|
| protocols.                                                                                       |
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Photo: Corbis

For example: In a 2010 trial at New York's Memorial Sloan Kettering Cancer Center, more than 90% of bladder-cancer patients failed to respond to the experimental treatment. But one 73-year-old patient's condition improved dramatically, with "no evidence of disease" two years later.

A genetic analysis of the tumor revealed a rare mutation—a "biomarker" in regulatory jargon—that made her cancer sensitive to the molecular pathway that the drug targets. Similar mutations were found by the Sloan Kettering researchers in about 8% of bladder-cancer patients—correlating with the tumor's sensitivity to the drug. The drug, already FDA-approved for kidney cancer, can be used off-label for treating bladder cancer.

Thanks to research like this, the National Cancer Institute (NCI) is currently analyzing a decade of other "failed" trials to examine whether it was the drugs that failed—or the FDA's clinical-trial protocols used to evaluate them.

The NCI has identified around 100 other exceptional responders—that is, the fewer than 10% of patients who responded to a targeted drug that wasn't generally effective for a specific disease or condition. If it turns out that the patients' tumors had genetic aberrations that matched targeted treatments, the studies could resuscitate drugs relegated to industry dustbins.

The discovery of molecular biomarkers is the foundation of truly personalized medicine. It allows biochemists to design targeted drugs to modulate these biomarkers, and doctors to prescribe the drugs to the right subset of patients.

The FDA recognizes the importance of biomarkers, but allows their use in framing clinical trials only when they have been "qualified." But for more than a decade it has engaged in a painfully slow and opaque case-by-case evaluation of each biomarker submission.

As a result, in most trials, new drugs are still prescribed in traditional fashion to a broad group of patients with the same clinically defined disease ("bladder cancer," for example) and are approved only if most patients respond positively.

These crowd-based trial protocols are, as a coalition of cancer experts from industry, academia and the FDA itself <u>noted</u> in 2010, "the antithesis of personalized medicine" and "expose large numbers of patients to drugs from which they may not benefit." The molecular processes propelling cancers and many other deadly diseases are extraordinarily complex. Asking researchers to identify every variation in patient-side chemistry that might affect a new drug's performance before a clinical trial begins would be wildly impractical and ruinously expensive. But, as demonstrated in the Sloan Kettering trial, every targeted drug can serve, in part, as a biomarker discovery and validation tool. A drug's selective efficacy helps researchers disassemble the targeted disease into a cluster of biochemically distinct disorders, launching the search for more drugs to fit newly discovered biomarkers.

This is exactly what is happening outside the FDA's rigid trial protocols.

Major cancer centers, including Dana-Farber in Boston and the Moffitt Center in Florida, are pooling data collected by oncologists, and using computers to develop precise biomarker-based prescription protocols using existing FDA-approved drugs. Commercial vendors are also offering precision oncology services recommending treatment based on patients' unique molecular profiles—regardless of what the drug's FDA-approved label says.

Still, the absence of accepted standards for how data are collected and analyzed for new drug approvals often limits collaboration among researchers and reduces financial incentives for investing in the development of new biomarkers. The participation of leading cancer centers in such programs reflects broad consensus that reliable biomarker science can be developed by studying a drug's performance during treatment, without rigid FDA failure/success scripting.

The National Cancer Institute plans to create a network to oversee and coordinate cancer drug

trials leading to "a new era of treatment trials that will carefully select the tumors that may

respond best to investigational therapy." Abroad, Britain is hatching plans to take the lead in

adopting 21st-century drug-trial protocols by creating a national framework for targeted drug

development.

At present, U.S. biomarker expertise is dispersed among numerous research centers and private

companies, and biomarker science will continue to improve much faster than any federal agency

can hope to evaluate it piecemeal. To keep pace, the FDA should defer to that expertise, relying

on consensus scientific standards to validate new biomarkers. By engaging the broader scientific

community, the agency can, at last, unleash the power of modern pharmacology and computing

to revolutionize medicine.

Messrs. Huber and Howard are senior fellows at the Manhattan Institute. They are the authors

of the forthcoming Manhattan Institute report, "Unlocking the Code of Health: Bridging the Gap

Between Precision Medicine and FDA Regulation."

Dorothy Jones-Davis, Ph.D.

Scientific Project Manager, Neuroscience

Division of Research Partnerships

Foundation for the National Institutes of Health

9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org

Direct (301) 594-2612 | BB (240) 515-0128 | Fax (301) 480-2752 | djones-davis@fnih.org

Combined Federal Campaign (CFC) #29165

Recipient of 4-star rating from Charity Navigator, 2007-2012



From: Jones-Davis, Dorothy (FNIH) [T]

Sent: Wednesday, February 04, 2015 1:35 PM

To: Wholley, David (FNIH) [T]; Canet-Aviles, Rosa (FNIH) [T]; Eason, Paula (FNIH) [T]; Hoffmann, Steve

(FNIH) [T]; Vassileva, Maria (FNIH) [T]; Whitaker, Sanya (FNIH) [T]; Ratay, Jessica (FNIH) [T]

Subject: Biomarkers in today's Wall Street Journal

Hello Research Partnerships Team:

I thought that you might be interested in this Wall Street Journal article, relevant to the discussion that Dr. Freire had with our team yesterday.

Best regards, Dorothy

Dorothy Jones-Davis, Ph.D. Scientific Project Manager, Neuroscience

#### Division of Research Partnerships

Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 594-2612 | BB (240) 515-0128 | Fax (301) 480-2752 | djones-davis@fnih.org

Combined Federal Campaign (CFC) #29165 Recipient of 4-star rating from Charity Navigator, 2007-2012



From: Energy and Commerce News [mailto:ECNews@ECREP.housecommunications.gov]

**Sent:** Wednesday, February 04, 2015 1:29 PM **Subject:** #Cures2015: Hope on the Horizon



Chairman Fred Upton

FOR IMMEDIATE RELEASE February 4, 2015 CONTACT: Press Office (202) 226-4972

# #Cures2015: Hope on the Horizon

### Manhattan Institute Senior Fellows Write about Hope for New Treatments

The goal from the beginning of the the 21st Century Cures initiative, launched last year by Chairman Fred Upton (R-MI) and Rep. Diana DeGette (D-CO), has been to accelerate the pace of cures in America. This means improving research efforts, streamlining the FDA approval process, and

creating a more efficient and effective health care system for each and every patient. But outdated rules can pose a hazard to potential new medical treatments. The Manhattan Institute's Peter Huber and Paul Howard write in today's <u>The Wall Street Journal</u>, "At the forefront of cancer treatment, rare responses to experimental drugs are helping rewrite the rules of drug development, rescuing seemingly failed medicines and saving lives along the way. The science behind these responses should lead to a broad rethinking of the FDA's clinical-trial protocols."

The duo highlights a "2010 trial at New York's Memorial Sloan Kettering Cancer Center, more than 90% of bladder-cancer patients failed to respond to the experimental treatment. But one 73-year-old patient's condition improved dramatically, with 'no evidence of disease' two years later. A genetic analysis of the tumor revealed a rare mutation—a 'biomarker' in regulatory jargon—that made her cancer sensitive to the molecular pathway that the drug targets."

# THE WALL STREET JOURNAL.

#### February 3, 2015

#### What Failed, the New Cancer Treatment or Regulators?

Bureaucracy and outdated rules too often block potential breakthroughs, but now hope is on the horizon.

Washington's leaders rarely focus on how bureaucracy and outdated regulations handicap the efforts of America's most innovative companies and researchers to bring new treatments to patients. But it's happening.

Last week the 21st Century Cures initiative—spearheaded by House Energy and Commerce Chairman Fred Upton (R., Mich.) and Rep. Diana DeGette (D., Colo.)—released a report offering bipartisan suggestions for streamlining clinical trials and reforming the Food and Drug Administration's regulation of emerging technologies. Sens. Lamar Alexande (R., Tenn.) and Richard Burr (R., N.C.) issued their own call for reform, arguing that "too many patients with no treatment options wait while potential treatments languish in laboratories."

Their efforts won't founder for lack of evidence.

At the forefront of cancer treatment, rare responses to experimental drugs are helping rewrite the rules of drug development, rescuing seemingly failed medicines and saving lives along the way. The science behind these responses should lead to a broad rethinking of the FDA's clinical-trial protocols.

For example: In a 2010 trial at New York's Memorial Sloan Kettering Cancer Center, more than 90% of bladder-cancer patients failed to respond to the experimental treatment. But one 73-year-old patient's condition improved dramatically, with "no evidence of disease" two years later.

A genetic analysis of the tumor revealed a rare mutation—a "biomarker" in regulatory jargon—that made her cancer sensitive to the molecular pathway that the drug targets. Similar mutations were found by the Sloan Kettering researchers in about 8% of bladder-cancer patients—correlating with the tumor's sensitivity to the drug. The drug, already FDA-approved for kidney cancer, can be used

off-label for treating bladder cancer.

Thanks to research like this, the National Cancer Institute (NCI) is currently analyzing a decade of other "failed" trials to examine whether it was the drugs that failed—or the FDA's clinical-trial protocols used to evaluate them. ...

The discovery of molecular biomarkers is the foundation of truly personalized medicine. It allows biochemists to design targeted drugs to modulate these biomarkers, and doctors to prescribe the drugs to the right subset of patients. ...

At present, U.S. biomarker expertise is dispersed among numerous research centers and private companies, and biomarker science will continue to improve much faster than any federal agency can hope to evaluate it piecemeal. To keep pace, the FDA should defer to that expertise, relying on consensus scientific standards to validate new biomarkers. By engaging the broader scientific community, the agency can, at last, unleash the power of modern pharmacology and computing to revolutionize medicine.

Read the full column online HERE.

###

**PERMALINK** 

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This email was sent to diones-davis@fnih.org using GovDelivery, on behalf of: House Committee on Energy and Commerce · 2125 Rayburn House Office Building, Washington, DC 20515

**From:** Freire, Maria (NIH/OD) [E] **Sent:** Sat, 15 Dec 2012 20:48:30 -0500

To: Collins, Francis (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

**Subject:** Fw: Collins funny on NPR

Another fan, Francis - and this was a spontaneous review! Wait, wait...is part of my Saturdays, so I heard it too; you WERE funny! I especially liked when you took the signal (or silence) from the audience - they ate it up. Smiling, M.

**From**: Rouse, Doris J. [mailto:rouse@rti.org] **Sent**: Saturday, December 15, 2012 06:14 PM

**To**: Freire, Maria (NIH/OD) [E] **Subject**: Collins funny on NPR

FYI-- I heard Francis Collins today on the NPR humor radio show "Wait, Wait, Don't Tell Me." He was very funny – a good sport.

For example, they asked him about legalizing medical marijuana. Collins responded that it was a topic that needed more research. The NPR fellow had the quick response of "And you are just the one to do that research, right?" Collins laughed as did everyone listening.

Have a great weekend!

Sent:Tue, 18 Jun 2013 15:45:56 -0400To:Collins, Francis (NIH/OD) [E]Cc:Burklow, John (NIH/OD) [E]Subject:Vignettes on the video

Attachments: Dr. Collins press clippings.docx

See, Francis.....



Video: Guitar Playing NIH Director Nails 'The Sequester Blues' By Mark Micheli

June 6, 2013

If you're not familiar with Dr. Francis Collins, Director of the National Institutes of Health, you should be. In addition to mapping the human genome and running the largest biomedical research facility in the world, he's also the most musically gifted federal official around.

Case in point: The video message he prepared for an awards dinner hosted by the Foundation for the National Institutes of Health (FNIH) last month. Unable to attend the ceremony, where Dr. Ruslan Medzhitov was awarded a \$100,000 prize for his pioneering research into the immune system, Collins ended his video congratulations with a performance of the original song, "The Sequester Blues."

From the more than \$30 billion NIH budget, sequestration is cutting \$1.7 billion from the institute's budget, which supports biomedical research in all 50 states. The budget cuts have raised concerns about the future of the biomedical workforce as the U.S. is one of the only developed nation's to recently reduce its investment in research and development.

#### From the FNIH website:

NIH Director Dr. Francis Collins provided a video and a song that set the stage at the FNIH Award Ceremony May 14, 2013, where the first annual Lurie Prize in Biomedical Sciences was awarded to Ruslan Medzhitov, M.D. Dr. Collins emphasized the importance of training the next generation of biomedical researchers to keep the discovery pipeline full of curious, innovative investigators to take advantage of today's remarkable opportunities for new breakthroughs in biomedicine.

Watch the video below: http://bcove.me/12fospdu

Want more of Collins' musical stylings? Check out video of his 2007 commencement address at the University of Michigan: http://www.youtube.com/watch?v=ob-r5MPa-ms&feature=player\_embedded



Francis Collins Sings About Sequestration -- June 6, 2013 link.brightcove.com Francis Collins Sings About Sequestration --June 6, 2013

Share



Like - Comment - Share



Write a comment...



Who knew @NIHDirector could sing? He emphasizes training the next generation of researchers in the #Sequester Blues: http://t.co/5eYB3YiFyf

10:36 AM - 12 Jun 13

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\* Favorite

# NIH Director Sings "The Sequestration Blues"

Sequestration and its effect on health research are hardly light-hearted topics for conversation. But to set the stage at the Foundation for the National Institutes of Health Award Ceremony last May, Francis S. Collins, MD, PhD, director of the National Institutes of Health, found one way to inject some levity into the discussion. Watch here as Dr. Collins introduces the first annual Lurie Prize in Biomedical Sciences, awarded to Ruslan Medzhitov, MD, and then sings a self-accompanied rendition of "The Sequestration Blues": http://bit.ly/15Xeu5l.

Read *Neurology Today*'s past coverage of sequestration and neurology research here: http://bit.ly/13CgpfD.

# Symbionticism **Symbionticism**

A blog about symbiosis and one of Life's great rules - Out of Many, One - b

**MONDAY, JUNE 10, 2013** 

# Francis Collins Performs "The Sequester Blues"

Quick thought here...the NIH director Francis Collins has the coolest double helix on the neck of his guitar. Definitely a must see. But perhaps the NIH Director should, respectfully, stick to his day job and claw us out of the sequester. Or maybe collaborate with BB King to amp up his performance. Now that could get some dollars flowing back at science. Here he is singing "The Sequester Blues" to commiserate with US scientists. Click this link to see the video.



http://bcove.me/12fospdu





# Video: Guitar Playing NIH Director Nails 'The Sequester Blues'

By Mark Michell | June 6, 2013 | 1 Comment



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FNIH

If you're not familiar with Dr. Francis Collins, Director of the National Institutes of Health, you should be. In addition to mapping the human genome and running the largest biomedical research facility in the world, he's also the most musically gifted federal official around.

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Watch the video below:

#### **RECENT POSTS**

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12:19 PM ET | 1 Comment

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June 14, 2013 | 1 Comment

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June 14, 2013 | 0 Comments

15 Things the Public **Has More Confidence** in Than Congress

June 13, 2013 | 15 Comments

Sent:Thu, 9 Oct 2014 17:41:58 -0400To:Collins, Francis (NIH/OD) [E]Subject:RE: FNIH Board meeting

Attachments: Board Agenda 30oct14 d4.docx

Hi, Francis. I hope you got to your IC meeting on time. Following the meeting with JB (which was fine but a bit odd, including lots of time on Ebola – him letting us know how much he knows), I went to the office for about an hour and then came home. I just woke up – ugh.

On the Board meeting: I have attached the draft agenda, where I have you speaking shortly after 9am. If your schedule permits, it would be great if you could call in for a few minutes and address the Board. I don't think we need a video link for that – you will have been with them the evening before, so nobody will fault you for not being supportive and active. Would that work? Timing is flexible, so I can work you in when it suits your schedule best.

As to the rest of the agenda: the Board needs to decide on the 2015 budget and 2 governance items (Board responsibilities and self-evaluation). If I may be so bold (and if I get Kathy the budget justification for her to send to the Steering Committee and if they approve), it might be a perfect opportunity for you to announce NIH's support of the Foundation by providing increased funding. Let me tell you, it will be an enormous boost for the Board! Obviously, those funds are not included in the budget we are submitting, which is very, very tight.

I will brief you fully on the other items when the three of us we next meet, so you need not worry about those. FYI, Peggy (who never attends) might do so this time. She is not on the agenda until I get that confirmed.

Does this sound like a good option? I will send the agenda for the dinner under separate cover. Best, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, October 09, 2014 3:27 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** FNIH Board meeting

Hi Maria,

I am definitely coming to the FNIH Board dinner on October 30 (I'll be shuttling back from Boston to be here in time).

But I'm having a lot of trouble figuring out how to also come to the Board meeting in person the next day, as it's an incredibly full day and travel back and forth to downtown adds another couple of hours.

Possible options: 1) have the discussions for which I am needed happen at dinner on 10/30

- 2) have me send Kathy in my place (not sure if she's available, but can check)
- 3) have me join by video

# Advice?

Hope you are feeling better and that JB didn't make you feel even worse!

FC

### DRAFT - DRAFT - DRAFT - DRAFT - DRAFT - DRAFT - DRAFT

### FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

# Board of Directors Meeting October 30, 2014

Location: Loews Madison Hotel

# Montpelier Room

# Note: All Times Eastern Daylight Time

## **CALL IN NUMBER**

Phone Number: 866-316-1519; Passcode: 48841618

# Agenda

| 8:00AM    | Breakfast – Hamilton B                               |                        |             |
|-----------|------------------------------------------------------|------------------------|-------------|
| 9:00AM    | Call to Order and Welcome                            |                        | Dr. Sanders |
|           | Approval of Minutes                                  | ACTION                 | Mrs. Blair  |
|           | Chairman's Report                                    | Information            | Dr. Sanders |
|           | Report from the Director, NIH                        | Information            | Dr.         |
| Collins   |                                                      |                        |             |
| · ·       | President's Report                                   | Information/Discussion | Dr.         |
| Freire    |                                                      |                        |             |
| 10:30AM   | BREAK                                                |                        |             |
| 10:45AM   | Communications Committee Report                      | Information/Discussion | Dr.         |
| Bloomgard | den                                                  |                        |             |
|           | Governance Committee Report - Board Responsibilities | Discussion/ACTION      | Dr. Snyder  |

#### DRAFT - DRAFT - DRAFT - DRAFT - DRAFT - DRAFT - DRAFT

- Board Self-Evaluation

Finance and Audit Committee Report

Discussion/ACTION Mr. Mayer

- 2015 Budget

PPP Committee Report Discussion Dr.

Sigal

- Program Highlight: MalED Dr. Gottlieb

Other Business

12:30PM Lunch - Hamilton B

1:30PM Executive Session

2:00PM Adjourn Dr.

Sanders

Next Board Meeting - May 21, 2015

Sent: Thu, 9 Oct 2014 19:31:58 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: Re: FNIH Board meeting

Yes, 10am will be great - should we make it 10:15 to give you some wiggle room? AMP may come up the night before in the AD discussion, which is the only reason I demur. You were so great on Ebola - maybe something on that and a potential role for FNIH, if needed? Let me noodle more on that and get back to you. Get some rest! M.

**From:** Collins, Francis (NIH/OD) [E] **Sent:** Thursday, October 9, 2014 7:23 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: FNIH Board meeting

Hi Maria,

Thanks for your flexibility. Since Oct. 30 is a Thursday, we have NIH Steering Committee from 8:30-10 AM, and I need to be present for that. Can I call in at 10 AM instead?

Please get the info to Kathy about the budget and let's see if we can make that work.

Are there things that you think the Board would want to hear from me? I assume I should say something about AMP.

NIH urgencies have forced me to stay up all day, but am getting close to hitting the wall. G'night.

FC

From: Freire, Maria (FNIH) [T]

Sent: Thursday, October 09, 2014 5:42 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** RE: FNIH Board meeting

Hi, Francis. I hope you got to your IC meeting on time. Following the meeting with JB (which was fine but a bit odd, including lots of time on Ebola – him letting us know how much he knows), I went to the office for about an hour and then came home. I just woke up – ugh.

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Sent: Thursday, October 09, 2014 3:27 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** FNIH Board meeting

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- 3) have me join by video

Advice?

Hope you are feeling better and that JB didn't make you feel even worse!

FC

 Sent:
 Fri, 17 Jul 2015 10:31:41 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Automatic reply: Note for Ann Ashby

I am on leave until July 22nd. For urgent matters, please contact Ms. Felicia Gray at fgray@fnih.org. Thank you.

**Sent:** Thu, 23 Jul 2015 12:56:45 -0400

To: Collins, Francis (NIH/OD) [E];Fauci, Anthony (NIH/NIAID) [E];Lane, Cliff

(NIH/NIAID) [E]

Subject: Chuckle - perhaps

#### CONFIDENTIAL

I thought you might find it interesting that Jeremy has just sent regrets. He will not be going to the Workshop in Hong Kong.

Tachi wants to invite you to call into the Hong Kong meeting; I have already told him and Anne Claiborne (IOM) that I had already suggested that but that it did not meet with rave reviews. Still, please don't be surprised if you get a note to that effect. Anne and I are suggesting a consultative meeting with USG officials in DC – NIH, FDA, BARDA, etc. That would be much better, I think.

I'll keep you posted. M.

**Sent:** Sun, 2 Jun 2013 17:50:37 -0400

To: Collins, Francis (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E]

Subject: David's son

Dear Francis and Kathy,

|  | (b) (6) |
|--|---------|
|  |         |
|  |         |
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 Sent:
 Fri, 13 Mar 2015 05:24:17 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: Deisseroth

Attachments: FNIH Award Ceremony - Dr. Collins Invitation.pdf

Hi, Francis. I missed our meeting this week, which luckily will be in a few days. During our discussion, I was going to ask you (on bended knee) if you would be willing to take an active role in the FNIH Award ceremony on May 20<sup>th</sup> with a conversation, on stage, with Karl. The two of you together would be dynamite; the audience will be absolutely mesmerized. Ann Lurie and Sol Snyder are so keen on the idea that they personally wrote you the formal invitation letter (included here). Please, please say yes! M.



March 3, 2015

Francis S. Collins, M.D., Ph.D. Director National Institutes of Health 1 Center Drive, Room 126 Bethesda, MD 20892-0148

Dear Dr. Collins,

This year marks the third annual Lurie Prize in Biomedical Research. As you know, the Foundation for the National Institutes of Health (FNIH) has bestowed this now sought-after honor on two fabulous recipients — Ruslan Medzhitov and Jennifer Doudna. This year we are delighted that the Lurie Prize Jury has selected another outstanding promising scientist, Karl Deisseroth, as the 2015 Lurie Prize recipient. The ceremony will take place on May 20 at 6:30pm at the Potomac View Terrace at the American Pharmacists Association in Washington, DC.

The centerpiece of the FNIH Award Ceremony is an informal and engaging interview with the Lurie Prize recipient. The idea is to get the audience, mostly non-scientists, excited about the winner's science and help them understand the impact and potential of the discoveries. It would be fantastic if you would be willing to conduct this 15 minute portion of the evening's program; your presence, your ability to communicate science and your outstanding command of the topic would mesmerize the broad audience in ways that would amplify his exciting research and the evening.

Francis, we hope you will consider this request positively; we cannot think of anyone better than you to do this.

Sincerely.

Ann Lurie

Honorary Chair

Solomon Snyder, M.D.

Chair, Jury Selection

 From:
 Freire, Maria (NIH/OD) [E]

 Sent:
 Thu, 20 Dec 2012 08:08:19 -0500

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: Ernesto"s CV Attachments: cv\_ef.pdf

Hi, Francis. We are looking forward to seeing you and Diane tonight. I thought you might want to peruse Ernesto's CV – he is actually quite well known for his "thermodynamic signature" in drug development, which can help predict potential best-in-class drugs, thereby increasing the chance of success of new chemical entities. Pharma and biotech companies are all over this... From his CV:

"In my laboratory, we are interested in the elucidation of the relationships between structure and energetics, and their applications to molecular design. In particular, we are interested in developing thermodynamic-based algorithms for structure-based drug design. These algorithms are aimed at achieving extremely high affinity, high selectivity and in the case of anti-infectives adaptability and low susceptibility to mutations associated with drug resistance. The algorithms developed in my laboratory integrate experimental microcalorimetric analysis with structure-based thermodynamic computations."







































































**Sent:** Mon, 25 Nov 2013 13:18:27 -0500 **To:** Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E];Burklow, John (NIH/OD) [E]

Subject: FDA to 23andMe: Stop Selling Kits Immediately

Francis, in case you have not seen this, from BIO-IT World. M.

**November 25, 2013** | The Food and Drug Administration issued a <u>warning letter</u> to 23andMe CEO Ann Wojcicki on Friday, saying the company was selling its spit kits and Personal Genome Service without marketing clearance or approval in violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act).

The direct-to-consumer personalized genomics test is "intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease," FDA contends, citing language on the 23andMe website heralding the service as the "first step in prevention".

FDA specifically highlighted concerns about 23andMe's assessment for BRCA-related genetic risk and drug responses. "For instance," FDA wrote, "if the BRCA-related risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist."

These are not new criticisms. The BRCA concerns, in particular, have been raised by many including Ellen Matloff, Director of the Cancer Genetic Counseling Center at Yale Cancer Center, at the <u>Consumer Genetics Conference in September</u>.

The FDA's letter exudes frustration, pointing out issues that 23andMe had "failed to address... during previous interactions with the Agency," saying further: "Since July of 2009, we have been diligently working to help you comply with regulatory requirements... However, even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses."

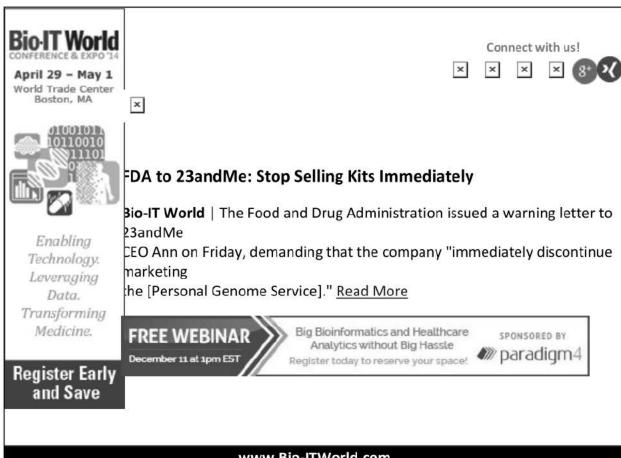
The letter states that FDA has not received any correspondence from 23andMe since May. That month, speaking at the <u>Big Data in Biomedicine conference</u> at Stanford University, Wojcicki announced that the company had dropped the price of genotyping to \$99 in hopes of getting one million customers by the end of the year and enable "really truly disruptive" research. In August, the company launched a <u>television marketing campaign</u>.

"We have become aware that you have initiated new marketing campaigns, including television commercials that, together with an increasing list of indications, show that you plan to expand the PGS's uses and consumer base without obtaining marketing authorization from FDA," the FDA's letter said.

The regulatory body's directive is clear: "23andMe must immediately discontinue marketing the PGS until such time as it receives FDA marketing authorization for the device."

At the time of writing, kits were still for sale on the 23andMe site.

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 Sent:
 Sat, 11 Apr 2015 07:10:27 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Evolution
Attachments: evolucion.PNG

Good morning, Francis. I could not resist sending you this. The translation is:

"Yes, honey, our ancestors had tails."

Have a great weekend. M.





## **EVOLUCIÓN**

**Sent:** Tue, 5 Nov 2013 06:59:12 -0500 **To:** Tabak, Lawrence (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: FNIH as an approved award giver

## Dear Larry,

I hope this finds you well and digging successfully from under the furlough e-mail mountain. I come to respectfully request that FNIH be reviewed to attain approval and be placed on the list of awards that have been cleared by NIH ethics review - ideally at the next ACD meeting.

The reason for the request, apart from the logical merit, is that such designation would have enormous impact on our ability to swiftly address pressing NIH needs, provide incentives or otherwise support NIH employees in their duties.

We could envision, for example, a travel award for a postdoc or a new PI to attend a meeting or conference, once he/she has been cleared to do so. The awards, in all likelihood, would be relatively small since we do not have excess resources we can tap, but they could transform the NIH experience for a scientist early in his/her career.

Having been one of the two members of the ACD that reviewed awards, I am well aware of the importance of being on the approved list and know that such a designation will serve NIH well because it would allow FNIH to exercise the authorities Congress provided in its authorizing legislation.

I am happy to chat about this further at your earliest convenience. All the best, Maria

**Sent:** Thu, 19 Sep 2013 10:32:26 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E];Gray, Felicia (FNIH)

[T]

Subject: FNIH Board dinner invitation

Attachments: Collins Invite.pdf

Dear Francis,

You will recall we have an upcoming Board meeting on October  $31^{st}$  (yes, Halloween – oy!) from 9:30am – 2pm at the Ritz Carlton in McLean, VA. We would very much welcome your participation and we hope you will be able make a short presentation. You are always inspiring and motivating.

Enclosed you will find an invitation to the Board dinner the evening before. I am modeling these dinners like the ones I started at Lasker, with 3 or 4 very short presentations (5 – 7 minutes) meant to provide fodder for informal discussion. Issues surrounding the brain (BRAIN and TBI) are the focus this time.

I hope you will be able to participate in both events. See you tomorrow at the Lasker Luncheon, Maria



September 18, 2013

Francis S. Collins, M.D., Ph.D. Director National Institutes of Health 1 Center Drive Room 126 Bethesda, MD 20892-0148

Dear Francis:

As you may recall, the next FNIH Board of Directors meeting will take place on Thursday, October 31, 2013 from 9:30am to 2pm, at the Ritz-Carlton Tysons Corner in McLean, Virginia. As is customary, we welcome your participation and would hope that you would agree to make a short presentation to the Board. We will, of course, find a time that will suit you best, should you be able to join us.

I would also like to invite you to come to the Board dinner, which will take place the evening before, October 30. This gathering provides an opportunity for informal discussion on topics of interest and import to medicine and biomedical research. This time, I have invited Dr. Elliot Pellman of the National Football League (NFL) to say a few words (5 to 7 minutes) about his perspective on the program the NFL has funded at FNIH. Traumatic brain injury is, indeed, a very timely and important topic. Likewise, I have also asked Dr. Story Landis to join us to get her perspective of the scientific challenges and opportunities in this field.

Given your leadership on the BRAIN project, I was hoping you could briefly comment on how our understanding and exploration of the brain can and will impact our future. It would provide an important perspective for all.

Francis, I hope you are able to attend both the dinner and the meeting.

With warm regards,

Maria C. Freire, Ph.D.

President and Executive Director

From: Freire, Maria (FNIH) [T]

**Sent:** Fri, 6 Jun 2014 19:44:29 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Cc: Wholley, David (FNIH) [T]

Subject: Fw: Answers to LungMAP questions

Francis, Kathy - I asked David for help in answering the questions on LungMap that arose during our conversation on Tuesday. Below are his replies.

Have a great weekend, Maria

From: Wholley, David (FNIH) [T] Sent: Friday, June 06, 2014 07:39 PM

To: Freire, Maria (FNIH) [T]

**Subject**: Answers to LungMAP questions

Maria,

Here are the answers to the questions Francis Collins asked you about LungMAP:



Please let me know if Francis needs any more information—we are happy to provide it.

David

From: Freire, Maria (NIH/OD) [E]

Sent: Thu, 1 Nov 2012 18:47:34 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: First day on the job...

Much to discuss and plan. All my best, always, M.

Hi, Francis! I feel like the kid that just started school – excited and nervous but very happy. Just wanted to say hello – I will take you up on your request/promise that we have standing meetings to catch up.

P.S. You will notice I show up as an NIH employee – thanks to being on the ACD!!! Interesting...

From: Freire, Maria (FNIH) [T]

**Sent:** Sat, 18 Jul 2015 09:11:21 -0400 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** FW: Catching up

Francis, FYI from John Porter.

(b) (6) Best, Maria

From: Porter, John E. [mailto:john.porter@hoganlovells.com]

Sent: Friday, July 17, 2015 10:45 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** Re: Catching up

I may be late with it.

(b) (6)

Sent from my iPhone

On Jul 16, 2015, at 11:06 PM, "Freire, Maria (FNIH) [T]" < freiremc@od.nih.gov > wrote:

Dear John,

(b)(6)

As you know, Ann Ashby will be leaving us at the end of the month. We are compiling a scrap book as a surprise for her with notes from people with whom she worked while she was here and, of course, you came to mind. Would you be willing to write a note to be included in the book? I know she would love that! If you decide to do se, we would need it by the middle of next week – we can print it for you if you send the letter, if this is easier for you.

Please do let us know if we can be of help. All the best, Maria

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From: Freire, Maria (FNIH) [T]

**Sent:** Mon, 8 Sep 2014 17:20:59 -0400 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** Fw: Chan Family Gift to Harvard University

Attachments: Harvard University Receives Transformational Gift for the School of Public

Health -Eng.pdf

Francis, FYI. I know Gerald well. He sent me this note early this morning. Good for him and, yes, he has been on that Board for over 30 years. We had lunch about a month ago - I guess we have a few more years to go!

From: Gerald Chan <GLChan@morningside.com> Sent: Monday, September 8, 2014 12:22 AM

To: Freire, Maria (FNIH) [T]

Subject: Chan Family Gift to Harvard University

Dear Maria,

We are delighted to share with you the good news that the Morningside Foundation is making a significant gift to Harvard University. This gift will strengthen the endowment of the Harvard School of Public Health. In recognition of this gift and in commemoration of the legacy of our late father Mr. T.H. Chan, Harvard has decided to rename the school as the Harvard T.H. Chan School of Public Health.

Our late father was an unwavering supporter of education. He wanted the enabling of education to be part of his legacy. Similarly, he wanted to support medical research for the alleviation of human suffering. It is therefore most fitting that his name be associated with the Harvard School of Public Health – Harvard being the premier research university of the world and its School of Public Health being a school dedicated to improving human health.

We are grateful for your friendship and support over the years and want to personally share this news with you. The press release from Harvard University describing this gift is enclosed.

With all best wishes,

Gerald Chan



### Harvard University Receives Transformational Gift for the School of Public Health

School will be renamed in honor of the late T.H. Chan

BOSTON, September 8, 2014 – Harvard University announced today that The Morningside Foundation, established by the family of the late Mr. T.H. Chan, has pledged \$350M to support the School of Public Health (HSPH) which last year began its second century of research and teaching with a campaign to address four global threats: pandemics, harmful physical and social environments, humanitarian crises, and failing health systems.

A formal announcement is scheduled for 12:30 p.m. on Monday, September 8 at HSPH. The event will be broadcast live at: http://www.harvard.edu/live-stream.

The gift of endowed funds is being made by The Morningside Foundation. The foundation has long supported higher education through student scholarships and professorships at universities in both North America and Asia, including a professorship in radiobiology at HSPH in 2012.

"The field of public health drives discoveries that lead to healthier, longer, more productive lives. This extraordinary gift from the Chan family will enable Harvard's School of Public Health to tackle intractable health problems and to translate rigorous research into action and policy worldwide," said Harvard University president Drew Faust. "The Chan family's generosity sends a signal to the world: this is the public health moment. We are honored by this gift; it will inspire a new generation of public health leaders."

"The Chan family's transformational gift will help us empower current and new generations of talented and diverse students and faculty to address the complex health threats challenging the US and the world," said HSPH Dean Julio Frenk. "Their commitment to education and their belief in the power of public health is an inspiration, and their generosity will ensure we have the resources to continue to develop the most innovative solutions that will enable millions of people to live longer and healthier lives, now and in the future."

According to Frenk, the gift will support students and faculty whose works are dedicated to slowing and reversing four global health threats:

- Old and new pandemics ranging from malaria to Ebola to obesity and cancer;
- Harmful physical and social environments ranging from air and water pollution to the impact of gun violence and tobacco;
- Poverty and humanitarian crises, including war and natural disasters;
- Failing health systems around the globe, which make healthcare unaffordable, inefficient, and inaccessible to many.

"The Chan family is deeply committed to the promotion of public health," said Chan family trustee Mr. Peter S.A. Edwards. "The family and its trustees are delighted to contribute to so distinguished a university as Harvard to create this permanent public benefit as a memorial to the late Mr. T. H. Chan."

"On behalf of my mother and my brothers, I want to express how pleased we are that the legacy of our late father can be honored by this gift to HSPH. He was a generous man who was a staunch supporter of education. He also wanted to support scientific research to alleviate human suffering. He would be very pleased with this gift today and all the good works that this gift will enable," said Harvard School of Public Health alumnus Dr. Gerald Chan, SM 75, SD 79, a spokesperson for The Morningside Foundation.

Dr. Chan earned his master's and doctorate degrees from HSPH in the 1970s. While he was a student there, his father visited the school. It is fitting that a gift from the family's foundation be given to HSPH in honor of Mr. T.H. Chan. In recognition of the gift, the school will be renamed the Harvard T.H. Chan School of Public Health.

Established in 1913, Harvard School of Public Health enters its second century with a long history of accomplishments by faculty and alumni, including the invention of the iron lung to treat polio; key discoveries that led to the creation of the polio vaccine; strategies that enabled elimination of smallpox and are now leading to the elimination of guinea worm disease; creation of the Designated Driver Campaign in the US; research that inspired stricter Clean Air Act regulations saving millions of lives; development of checklists that made surgery safer worldwide; and research that linked trans fats to heart disease, including subsequent successful efforts to remove most trans fats from the food supply. The School has more than 400 faculty members and teaches 1,000-plus full-time students from more than 60 countries and 39 US states and Washington D.C.

The Campaign for Harvard School of Public Health was launched in 2013 as part of the University's capital campaign. The Chan gift represents the largest single donation in Harvard's 378-year history.

More information on Harvard University and the Harvard School of Public Health is available on their websites.

###

From: Freire, Maria (FNIH) [T]

 Sent:
 Sat, 18 Apr 2015 07:07:18 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: Fw: Follow-up

#### Yes!

From: Steven Paul <steve@thirdrockventures.com>

Sent: Thursday, April 16, 2015 6:06 PM

To: Freire, Maria (FNIH) [T]

Cc: steve@voyagertherapeutics.com

Subject: Re: Follow-up

Sounds great Maria! Thanks for your support!

Best, Steve

Sent from my iPad

On Apr 16, 2015, at 10:07 AM, Freire, Maria (FNIH) [T] < freiremc@od.nih.gov > wrote:

Hi, Steve. As promised, I discussed with Charlie, Francis and Sol (Governance Committee) the option of having you start as co-chair with Charlie this time next year with the transition to Chair after your IPO, no later than September 2016. They thought it was a terrific idea – although Francis wanted a date certain. So, we are in business! Are we agreed? M.

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From: Freire, Maria (FNIH) [T]

**Sent:** Fri, 13 Sep 2013 06:30:50 -0400 **To:** Burklow, John (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E];Battey, James (NIH/NIDCD) [E];Landis, Story

(NIH/NINDS) [E]; Sieving, Paul (NIH/NEI) [E]

**Subject:** Fw: NIH support for Blake's projects

Attachments: Acknowledgments section from the book Better Hearing with Cochlear

Implants\_highlighted for Maria.pdf, Chapter 1 from the book Better Hearing with Cochlear Implants.pdf,

Dedication.pdf

Hi, John. Blake Wilson and his colleagues just won the Lasker for clinical research. Out of habit, I asked Blake about his NIH support. His gracious answer is below, which I am sharing with you, Francis, Jim, Story and Paul. All the best, Maria

From: Blake Wilson [mailto:blake.wilson@duke.edu] Sent: Thursday, September 12, 2013 04:20 PM

To: Freire, Maria (FNIH) [T]

Subject: NIH support for Blake's projects

Dear Maria,

You very kindly asked about the support for my work – and the work of my teams – to develop cochlear implants. As I mentioned, the great majority of the support was from the NIH, first from the NINDS from September 1983 through April 1989, and then from the NIDCD from May 1989 through March 2006. Most of my NIH projects were administered through the Neural Prosthesis Program (NPP), which was a part of the NINDS for the entire period but received additional funding from the NIDCD, the Eye Institute, and other institutes within the NIH through cooperative agreements.

Some further information about the support and the key roles NIH played in the development of cochlear implants is presented in a recently published book that I wrote with Michael Dorman (<a href="http://www.pluralpublishing.com/publication\_hcirrti.htm">http://www.pluralpublishing.com/publication\_hcirrti.htm</a>). I have attached the Acknowledgments section and the overview chapter from the book in case you would like to see this additional information. The parts about the NIH support and roles are highlighted in the Acknowledgments section with the yellow background on pages ix and xi, and the information about the NIH in the overview chapter is presented on pages 3 and 4.

The book is dedicated to Terry Hambrecht, Bill Heetderks, and Michael Pierschalla. Terry and Bill were the directors (at different times) of the NPP and were the monitors for my projects and the many other projects within the NPP. Terry and Bill were (and are) magnificent, and they contributed mightily to our shared successes. Michael was an exceptional research subject who spent more than an integrated person-year in participating in our studies. I have attached the dedication as well.

Terry and Bill will be at the Lasker ceremony, as will Jim Battey, who as you no doubt know is the present Director of the NIDCD.

Thank you again for your wonderful congratulations Maria! They mean the world to me and you are so very gracious!

Doris and I very much look forward to seeing you in the big city!

Best, Blake

# **ACKNOWLEDGMENTS**

An exceptionally large number of organizations and highly talented and dedicated investigators contributed to the research described in this book. In addition, the research would not have been possible without the generous contributions of time by the many cochlear implant users who participated in the studies.

The research was supported primarily by the National Institutes of Health (NIH), through its Neural Prosthesis Program (NPP). The first project began in September 1983 and the final of the seven contiguous projects ended in March 2006. Funding for our particular projects within the NPP was provided by the National Institute of Neurological Disorders and Stroke (NINDS) for the first two projects and by the National Institute on Deafness and Other Communication Disorders (NIDCD) for the remaining projects. Funding by the NIDCD began on May 1, 1989.

In addition, a study involving subjects fitted with an experimental version of the Nucleus cochlear implant device was jointly supported by the NIH and Cochlear Americas Corp. This study began in the spring of 1994.

Travel expenses for visiting subjects and guest scientists also were generously covered by the MED-EL GmbH for studies involving: (1) recipients of bilateral MED-EL implants; (2) users of combined electric and acoustic stimulation of the auditory system; (3) users of the newly introduced MED-EL PULSAR implant system; and (4) a subject implanted on one side for amelioration of intractable tinnitus and who had nearly normal hearing on the other side. MED-EL additionally provided important technical assistance in these studies.

Most of the work was conducted at the Research Triangle Institute (RTI) in the Research Triangle Park in North Carolina. RTI is a large, not-for-profit research institute that was created in 1958 by the three largest research universities in the area, Duke

University, North Carolina State University, and the University of North Carolina at Chapel Hill. The present staff at the RTI includes more than 2,800 people at multiple locations in the United States and in other countries. The RTI is also known as RTI International, a trade name for RTI.

In addition, a substantial fraction of the research was conducted at the Duke University Medical Center in Durham, North Carolina. The great majority of patient studies were conducted there until the fall of 1995, when two new laboratories were built at the RTI. Use of the laboratory at Duke was tapered down to zero over the ensuing two years and, ultimately, all studies were conducted in the RTI laboratories.

At the outset of our work in 1983, and up until mid-1985, studies with research subjects were conducted at the University of California at San Francisco (UCSF). The projects required collaboration with a tertiary care center that was active in the clinical application of cochlear implants. When the projects began, the only such centers in the United States were at UCSF, Stanford University in Palo Alto, California, and the House Ear Clinic in Los Angeles, California. UCSF graciously agreed to be our collaborating clinical center.

A cochlear implant program was created at Duke in early 1985. Soon thereafter, the laboratory was created at Duke for cochlear implant studies, and space and funding for the laboratory were generously provided by David C. Sabiston Jr., MD, who was the Chair of the Department of Surgery. Once the laboratory was operational, most studies were transferred from UCSF to Duke with enthusiastic technical support by—and ongoing collaboration with—UCSF.

The members of the RTI teams over the years included the people listed in Chapter 1, under the subheading "Composition of the RTI Teams." Each of the members contributed strongly to the overall effort.

A hallmark of the projects was collaboration with many investigators, universities, and companies worldwide. Lists of the collaborating investigators and their affiliations at the times of their participation in the RTI studies are presented in Appendix A. Among the investigators, special acknowledgements are due to Michael M. Merzenich, PhD, who welcomed us into his program at UCSF at the beginning of our work when we had

little to offer in return, and Joseph C. Farmer Jr., MD, who asked us to conduct patient studies at Duke and supported our efforts with the highest enthusiasm thereafter.

Spectacular support also was provided by the management at the RTI. All requests for equipment were approved, and ample space and other resources were provided throughout the course of the projects. Special thanks are due to George R. Herbert, who was RTI's president during the early years of the projects; Grace C. Boddie, who was a vice president and the chief counsel for the Institute during the same period; and F. Thomas Wooten, PhD, who was the vice president of the Electronics and Systems Division within the RTI from 1983 to 1989 and became RTI's president in 1989 when Mr. Herbert retired. All of these and many other great people at the RTI supported the projects strongly.

Of course, we could not have done anything without our research subjects. We were blessed with some of the best, and we were continually amazed by their engagement in the studies and by their generosity in spending time with us.

We were blessed as well to be a part of the NPP. The heads of that program, F. Terry Hambrecht, MD, and, later, William J. Heetderks, MD, PhD, fostered a collaborative spirit among the participants in the program. For example, a Neural Prosthesis Workshop was held each year at NIH to review the progress of the many projects within the NPP and for the investigators to interact and share ideas. The cross-pollination of ideas was impressive, and advice was freely given and received. Everyone and each of the projects benefitted, and these benefits were made possible by the positive tone set by Terry and Bill.

Terry and Bill also were the project monitors for our projects. Terry and then Terry and Bill made regular site visits to our laboratories to review progress, plans, and problems that had been encountered. In addition, they read our progress reports carefully and communicated with us frequently about the work and especially about new ideas.

The site visits were both intense and rewarding. Terry and Bill never failed to offer the most insightful suggestions imaginable, including suggestions for solving problems, for new hypotheses, and for refined or new research directions. The guidance so selflessly provided by these two brilliant and dedicated leaders of the NPP was vital to our successes.

This book was made possible with the generous and highly able assistance of Susanne Stoops, Jeannie H. Cox, Callen Shutters, Dewey T. Lawson, and Stefan M. Brill. We are especially indebted to Susanne for her many efforts in helping to produce the book, including her expert transformation of the selected sections from NIH progress reports into the manuscripts for Chapters 2 through 21.

In addition, we are deeply indebted to the spectacular team at Plural for their sterling and highly professional efforts. The team members we worked with included Caitlin Thompson Mahon, Angie S. Singh, Kim White, Judy Meyer, Mandy Licata, Casey Stach, Stephanie Meissner, and Sandy Doyle. We are sad to announce that Sandy is now deceased; she helped us greatly with the graphics aspects of the book. Among the many contributions by the Plural team, Caitlin's editorial and production work stands out. She is the best of the best.

The concept for this book was suggested by Professor Michael F. Dorman many years ago. Although I thought the concept was wonderful, I kept delaying the project due to the press of ongoing activities and obligations. He persisted, however, and even offered to write the book with me. We finally began working on the book in earnest in the winter of 2011. I will forever be grateful to Michael for the concept, and for his perseverance, cheerful encouragement, and many key contributions to the writing. Indeed, those contributions and his guiding hand produced a book that is very much better than any book I could have written on my own.

Our RTI teams were privileged to have had the grand opportunity to pursue the work described herein. We were helped mightily every step of the way.

Blake Wilson, July 2011

There are only a few times in a career in science when you get goose bumps. One of mine came when one of my patients, Max Kennedy, was being tested at RTI with a version of a continuous interleaved sampling (CIS) processor. I was watching Dewey Lawson input Max's responses to the monitor program and Max's responses keep coming up "correct." Near the end of the test,

everyone in the room was staring at the monitor wondering if Max was going to get 100 percent correct on a difficult test of consonant identification. He came close, and at the end of the test, Max sat back, slapped the table in front of him, and said loudly, "Hot damn, I want to take this one home with me." I am indebted to Blake, Dewey, Charlie, and Marian for the goose bumps.

Michael Dorman, August 2011

## Chapter 1

# **OVERVIEW**

## Blake S. Wilson and Michael F. Dorman

As recently as the early 1980s, the success of cochlear implants (CIs) was very much in doubt. Indeed, it seemed that the more a researcher knew about auditory neurophysiology or speech acoustics, the more confident he was that implants could not provide a high (or even useful) level of speech understanding. Fortunately, pioneers in the implant field persisted in the face of doubt and, at times, intense criticism, and provided the foundation for the extremely successful CI devices that are available today.

Three large steps were needed to produce the present-day CIs: (1) the pioneering step to implant the first patients and to develop devices that were safe and had a life span of many years; (2) the development of devices that provided multiple sites of stimulation in the cochlea to take advantage of the tonotopic organization of the auditory system; and (3) the development of highly effective processing strategies that utilized the multiple sites of stimulation and supported for the first time high levels of speech recognition for most users of CIs. Findings from the landmark "Bilger study" in 1977 (Bilger et al., 1977)—and from the two consensus development conferences on cochlear implants held at the National Institutes of Health (NIH) in 1988 and 1995 (National Institutes of Health, 1988, 1995)—indicate the status of CIs at each of these steps. Principal conclusions from the Bilger study and the two consensus statements are presented in Table 1-1. As noted there, especially large gains in performance were obtained in step 3.

**Table 1–1.** Major Indicators of Progress in the Development of Cochlear Implants

| Persons or<br>Event                       | Year | Comment or Outcome                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Bilger et al.                             | 1977 | "Although the subjects could not understand speech through their prostheses, they did score significantly higher on tests of lipreading and recognition of environmental sounds with their prostheses activated than without them." (This was an NIH-funded study of all 13 implant patients in the United States at the time.) |
| First NIH<br>Consensus<br>Statement       | 1988 | Suggested that multichannel implants were more likely to be effective than single-channel implants, and indicated that about 1 in 20 patients could carry out a normal conversation without lip-reading. (The world population of implant recipients was about 3,000 in 1988.)                                                  |
| Second NIH 1995<br>Consensus<br>Statement |      | "A majority of those individuals with<br>the latest speech processors for their<br>implants will score above 80% correct<br>on high-context sentences, even without<br>visual cues." (The number of implant<br>recipients approximated 12,000 in 1995,<br>and the number exceeded 220,000 in<br>late 2010.)                     |

Teams at the Research Triangle Institute (RTI) in North Carolina, USA, along with their many collaborating investigators from other research organizations worldwide, contributed significantly to step 3. This book describes the program of research at the RTI and the collaborating organizations, and presents key results selected from nearly 23 years of research.

# THE RTI PROJECTS AND THEIR MEMBERSHIP IN THE NEURAL PROSTHESIS PROGRAM

As noted in the Acknowledgments, the research was supported primarily by the NIH, beginning in September 1983 and continuing through March 2006. In all, seven projects were supported. Each project had the title "Speech processors for auditory prostheses," but a wide range of studies and activities was included in the projects that went well beyond the design and testing of novel speech processors. A list of the projects with their terms and NIH numbers is presented in Table 1–2.

The projects were a part of the Neural Prosthesis Program (NPP) at the NIH, which supported work in the many different

**Table 1–2.** The Series of "Speech Processors" Projects at the Research Triangle Institute

| Project | NIH Number    | Term                                           |
|---------|---------------|------------------------------------------------|
| 1       | N01-NS-3-2356 | 26 September 1983 through<br>25 September 1985 |
| 2       | N01-NS-5-2396 | 26 September 1985 through<br>30 April 1989     |
| 3       | N01-DC-9-2401 | 1 May 1989 through 31 July 1992                |
| 4       | N01-DC-2-2401 | 1 August 1992 through 31 July<br>1995          |
| 5       | N01-DC-5-2103 | 1 August 1995 through<br>29 September 1998     |
| 6       | N01-DC-8-2105 | 30 September 1998 through<br>31 March 2002     |
| 7       | N01-DC-2-1002 | 1 April 2002 through 31 March<br>2006          |

4

areas relating to neural prostheses, for example, reambulation of paralyzed limbs or extremities; restoration of bladder control for quadriplegics; restoration of sensory inputs to the brain including auditory, visual, and vestibular inputs; brain-machine interfaces; packaging of implanted electronics; insulation for the nonactive parts of stimulating electrodes; alternative electrode designs for various neural prostheses; alternative stimulus designs; and safety of electrical stimulation.

Our area was restoration of auditory inputs to the brain, and our projects were accompanied by others in that same area. The projects at the RTI spanned the entire period from 1983 to 2006, and each of the other projects relating to auditory prostheses spanned shorter periods within those years. At the outset, our projects were the only projects directed primarily at better speech processor designs. In later years, either two or three projects on this topic were supported at any one time up until 2006 when the projects ended and the NPP had been reorganized into smaller units across multiple institutes at the NIH. (The reorganization occurred in 2004 and followed Bill Heetderks' decision in late 2002 to resign from his position as the Head of the NPP, so that he could accept an offer to become the Director of Extramural Programs at the newly created National Institute on Biomedical Imaging and Bioengineering; the NPP ceased to exist as a single entity with the reorganization.) These other "speech processors" projects were conducted at Stanford University in Palo Alto, CA: the University of Melbourne in Melbourne, Australia; the House Ear Institute in Los Angeles, CA; and the Massachusetts Eye and Ear Infirmary (MEEI) in Boston, MA.

Among the companion projects, we had an especially close and productive relationship with the team and projects at the MEEI. We developed portable speech processors together, and Don Eddington and Bill Rabinowitz of the MEEI team made important contributions to the development at the RTI (and Duke University Medical Center) of an especially effective and enduring processing strategy for CIs: the continuous interleaved sampling (CIS) strategy. This partnership leveraged the NIH support of the projects in Boston and North Carolina, in that we could accomplish more together than separately.

### QPRs—Four a Year for Over Twenty Years

Projects within the NPP were supported through the contracts mechanism, which was in accord with an integrated and coordinated program to develop better neural prostheses. Requirements of the contracts included presentations by the project teams at the annual Neural Prosthesis Workshop at the NIH; a detailed report of progress and problems encountered during each quarter for each of the projects; and a final report for each of the projects. The quarterly progress reports (QPRs) included a section on plans for the next quarter for all quarters except the final quarter, and the final reports (FRs) included a section on recommendations for future research. The progress reports provided a comprehensive record of activities and achievements for each of the projects.

In all, 91 reports were produced during the seven projects at the RTI. The authors and principal topic(s) for each of the reports are presented in Appendix B, which includes a separate table for each of the seven projects.

### A Very Costly Decision

Soon after the outset of the NIH projects, the RTI team at the time recommended a policy to its management for the handling of intellectual property (IP). The recommended policy was to donate all results from the NIH-sponsored research on CIs at the RTI to the public domain. The thought was that, with the inventions and other IP in the public domain, all valuable discoveries would be applied by most or all of the major manufacturers of CIs and thereby help the greatest possible number of deaf and severely hearing-impaired people.

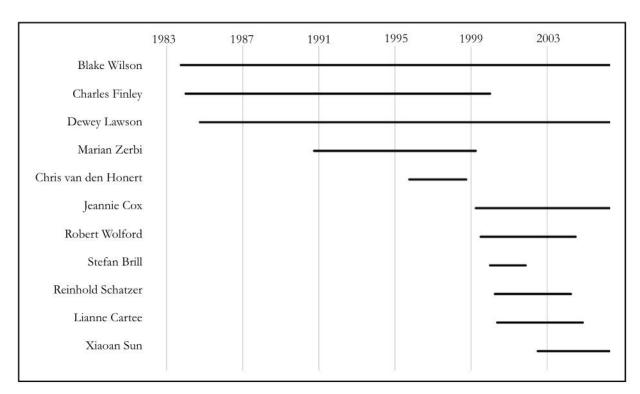
George R. Herbert, President of the RTI, and Grace C. Boddie, General Counsel, approved the policy after careful consideration of its implications, including the relinquishing of the Institute's rights to the IP as specified by the Bayh-Dole act, which was enacted by the United States Congress in 1980. The act specified that organizations conducting research under Federal grants or contracts would have the right to retain and pursue

IP resulting from the research, so long as the Government had a nonexclusive license to utilize the IP for its own purposes. The decision to forgo potential royalties from patents and exclusive licensing agreements proved to be important in that it greatly facilitated incorporation of discoveries from the RTI projects into commercially-available CI systems at the earliest possible times. In retrospect, the negative economic consequences of the decision to approve the policy were enormous (in the 10s of millions of dollars), both to the organization and to the individual inventors. However, the policy did what it was supposed to do, and the outcomes were most gratifying to the RTI teams and management.

### Composition of the RTI Teams

Members of the RTI teams over the years included Stefan M. Brill, Lianne A. Cartee, Jeannie H. Cox, Dee Dee Davis, Charles C. Finley, Kathrinn Fitzpatrick, Dewey T. Lawson, Reinhold Schatzer, Xiaoan Sun, Christopher van den Honert, Sandra Waters, Blake S. Wilson, Robert D. Wolford, and Mariangeli Zerbi. Kathrinn Fitzpatrick, Sandra Waters, Dee Dee Davis, and Jeannie H. Cox each served as the Administrative Assistant (AA) for the projects at different times in the program, and the remaining individuals served as investigators. (Jeannie Cox also assisted in patient studies in her later years in the program.) The projects were directed by Blake Wilson until he was appointed as one of the first four Senior Fellows at the RTI in late 2002. After that, Dewey Lawson became the Principal Investigator for the remainder of the final project in the series of the seven "speech processors" projects at the RTI.

A chart showing the times of service for most members of the teams is presented in Figure 1–1. As noted in the Acknowledgments, the RTI teams were assisted by many other investigators from many other research institutions worldwide, including institutions in Australia, Austria, Canada, Germany, Poland, South Korea, Spain, Switzerland, the United Kingdom, and the United States.



*Figure 1–1.* Composition of the RTI teams from 1983 to 2006. In addition to the members shown, Kathrinn Fitzpatrick, Sandra Waters, and Dee Dee Davis each served as the Administrative Assistant for the projects at different times from 1983 to 1999.

### ORGANIZATION OF THIS BOOK

In the remaining chapters of this book, we present the most important sections from the most important progress reports, in part to provide a convenient access in one place to the key studies and their results. Many journal articles and book chapters also were produced as part of the projects, but they were generally brief and limited to particular studies and therefore do not provide the detail or the coverage of the progress reports. In addition, the journal articles and book chapters may be obtained easily from libraries and the web, whereas the progress reports are not as widely available.

Another reason to present material from the progress reports is that the reports convey the essence of the projects from start to finish. The journal articles fail to do that because they describe single studies only, as just mentioned, and the book chapters fail to do that because they generally integrate results from across many laboratories and areas of research to provide a tutorial for their readers. The journal articles and book chapters are cited at the appropriate places throughout the book, but the emphasis here is on the progress reports.

Following this overview chapter, the book is organized into major parts according to the principal areas of research in the RTI projects, including design and evaluation of novel processing strategies; electrical stimulation on both sides with bilateral CIs; combined electric and acoustic stimulation of the auditory system; and representations of temporal information with CIs. Multiple chapters are included in each part, and each chapter is a selected section from a progress report. In addition, each part includes a brief introduction to indicate its contents and to point to other relevant reports and findings that could not be included in the book. The references originally cited in the selected sections from the selected progress reports are now presented in the single list of references at the end of this book. Also, some of the figures have been redrafted to provide high-resolution images. Otherwise, no changes have been made in the included source material other than formatting changes in the text for a uniform style and correction of typographical and other minor errors.

In the remainder of the present chapter, we: (1) describe the role of the RTI projects in the broader context of the development of CIs; (2) indicate how we selected the sections from the NIH progress reports for inclusion in the book; and (3) offer some concluding remarks.

# RTI'S ROLE IN THE DEVELOPMENT OF COCHLEAR IMPLANTS

In 1983, when the first project at RTI was underway, the first of the three steps listed near the beginning of this chapter had been taken and progress was being made in taking the second step. Dr. William F. House and a few other pioneers had implanted the first patients, and Dr. House in particular had developed singlechannel devices that could be safely and usefully applied over many years. In addition, groups in the United States, Australia, and Europe had developed multielectrode arrays that could be safely inserted at surgery in the scala tympani of the cochlea and that could excite different sectors (or tonotopic regions) of the auditory nerve depending on which intracochlear electrode, or which closely spaced pair of intracochlear electrodes, was activated. However, high levels of speech recognition using hearing alone was still rare and even as late as 1988 only about one in 20 patients using any of the better multisite and multichannel implants could carry out a normal conversation without lip-reading (National Institutes of Health, 1988; see Table 1-1). The implant systems in 1983 were mainly useful as an adjunct to lip-reading and for an awareness of environmental sounds. In the rare cases, a patient could understand high-context sentences with her or his restored hearing alone. Those best performances were far below what was to come later with some further refinements in multisite stimulation and with the completion of step 3. In addition, the completion of step 3 allowed most patients to attain high levels of sentence recognition with hearing alone, as opposed to the small fraction of patients in 1988.

### Step 3 and the CIS Strategy

The largest contribution from the RTI projects was in the completion of step 3, as mentioned previously. In particular, multiple

new ways to represent speech and other sounds with CIs were created in the projects, and these new ways supported high levels of sentence recognition using hearing alone for the great majority of implant users. Perhaps the best known discovery came in 1989 and was first called the "supersampler" strategy and then soon thereafter the CIS strategy (Wilson et al., 1989).

Results from the initial studies with the CIS processor were reported in *Nature* in 1991 (Wilson et al., 1991a). This paper soon became the most highly cited publication on studies with CI patients and remains as the most highly cited publication on the topic today. As of July 2011, the paper had been cited in 476 other peer-reviewed publications (Web of Knowledge, 2011).

CIS was a combination of new and prior elements, including: (1) a full representation of energies in frequency bands spanning the spectrum of speech and other sounds; (2) no further analysis of, or "feature extraction" from, this or other information, to allow the brain of the user to make the decisions about what was important or not important in the incoming stream of information; (3) nonsimultaneous stimulation with charge-balanced biphasic pulses across the electrodes in a multielectrode implant, to eliminate the component of electrode or "channel" interactions due to direct summation of overlapping electric fields from the electrodes for simultaneously presented stimuli; (4) stimulation at relatively high rates at each of the electrodes, to allow representations of fundamental frequencies for periodic sounds such as voiced speech and of distinctions between periodic versus aperiodic sounds such as unvoiced speech (again, without explicit extraction of these "features"); (5) use of cutoff frequencies in the energy (or "envelope") detectors for each of the bandpass filters that would include the fundamental frequency variations in the outputs of the detectors (cutoff frequencies in the range of 200 to 400 Hz); (6) use of current sources rather than the relatively uncontrolled voltage sources that had been used in some prior implant systems; and (7) a relatively high number of activated electrodes (at least four but generally higher and not limited in number). No assumptions about sounds in the environment, or in particular how speech is produced or perceived, were made in the way CIS was constructed. This approach allowed the brain of the user to become a far more active and important part of perception with CIs.

It is worth noting that the gains in performance produced with CIS are sometimes attributed to the non-simultaneous stimulation across electrodes. However, the gains were produced with the discovery of a unique combination of many elements, not just non-simultaneous stimulation, which had been used before (see, e.g., Doyle et al., 1964) but not in conjunction with the other elements. The breakthrough was in the combination and in exactly how the parts were put together.

### Step 3 and "n-of-m" or Channel-Picking Strategies

During the late 1980s and early 1990s, the RTI teams and their collaborating investigators created multiple other ways to represent speech and other sounds with multisite and multichannel implants. These ways included the n-of-m approach that was subsequently incorporated in a line of processing strategies developed for implant devices manufactured by Nucleus Ltd. and later by Cochlear Pty. Ltd., of Lane Cove, Australia. (Nucleus was the parent company for Cochlear.) The n-of-m approach is a variation of CIS in which the envelope signals for the different bandpass channels are "scanned" prior to each frame of stimulation across the intracochlear electrodes, to identify the signals with the n-highest amplitudes from among a total of m processing channels (and associated intracochlear electrodes). Stimulus pulses are delivered only to the electrodes that correspond to the channels with those highest amplitudes. (The n-of-m approach actually was created before CIS; describing the *n*-of-*m* approach as a variation of CIS is a retrospective description.)

This channel selection or "spectral peak picking" scheme is designed in part to reduce the density of stimulation while still representing the most important aspects of the acoustic environment. The deletion of low-amplitude channels (and associated stimuli) for each frame of stimulation may reduce the overall level of masking or interference across electrode and excitation regions in the cochlea. To the extent that the omitted channels do not contain significant information, such "unmasking" may improve the perception of the input signal by the patient. In addition, for positive signal-to-noise ratios, selection of the channels with the greatest amplitudes in each frame may emphasize the primary speech (or other) signal with respect to the noise.

The *n*-of-*m* approach was first described for relatively low rates of stimulation in a QPR in 1986 (Wilson et al., 1986; also see Wilson et al., 1987, 1988a). The approach was the basis for the "spectral maxima sound processor" (SMSP) developed in Melbourne, Australia, in the early 1990s (McDermott et al., 1992; McDermott & Vandali, 1997) and later applied in slightly modified form as the "spectral peak" (SPEAK) strategy, which was used as a part of the Nucleus and Cochlear CI systems for many years thereafter. The patent for the SMSP (McDermott & Vandali, 1997) cites Wilson et al. (1987, 1988a) as the "prior art," and primarily specifies desirable values for the parameters *n* and *m*.

Soon after the creation of CIS, the RTI team at the time suggested that the relatively high rates of stimulation and other attributes of CIS might be beneficial for the *n*-of-*m* approach as well (Lawson et al., 1995; Wilson et al., 1995a, 1995b). This suggestion led to a large project at the RTI that was jointly supported by the NIH, Cochlear Pty. Ltd., and the Duke University Medical Center. An important aim of the study was to evaluate the suggestion, and the resulting data affirmed it fully (e.g., Lawson et al., 1996).

Some years later, Cochlear Pty. Ltd. introduced the "advanced combination encoder" (ACE) strategy, which used the *n*-of-*m* approach in conjunction with the relatively high rates of stimulation and other attributes of CIS. This strategy quickly became the default processing option for the Cochlear devices and remains as the default option today.

The "high rate" *n*-of-*m* strategy, as described and evaluated by the RTI team, also is used as a processing option in a series of CI systems manufactured by MED-EL GmbH of Innsbruck, Austria. The option is called the *n*-of-*m* strategy in those systems.

## Step 3 and the Virtual-Channel Strategy

The RTI team also created a way to utilize virtual pitches in a multichannel processor context (e.g., Wilson et al., 1992, 1994). In that approach, pairs of adjacent intracochlear electrodes were stimulated simultaneously to produce pitches that were intermediate to the pitches produced with stimulation of either electrode in the pair alone. Each pair in the electrode array was stimulated after stimulation of the prior pair, maintaining nonsimultaneity

of stimulation across the pairs (and regions of stimulation in the cochlea). Other aspects of CIS were retained as well, and these processors were called "virtual channel interleaved sampling (VCIS) processors."

The production of intermediate pitches with simultaneous stimulation of two electrodes had been described before, first by Simmons et al. in 1965 for electrodes implanted directly within the auditory nerve and then by Townshend et al. in 1987 for electrodes implanted in the scala tympani (Simmons et al., 1965; Townshend et al., 1987). The RTI group was the first to describe the use of intermediate pitches in a multichannel context and among multiple pairs of electrodes. The VCIS approach was later used in a processing strategy developed by the Advanced Bionics Corp. (ABC) of Valencia, CA, USA (e.g., Trautwein, 2006). The strategy in the ABC devices is called the "Hi-Resolution 120" or HiRes 120 strategy.

In the early development of VCIS processors, the RTI team showed that with appropriate current biasing a pitch percept could be created that was: (1) lower than the pitch percept produced by stimulation of the most apical electrode in the array or (2) higher than the pitch produced by stimulation of the most basal electrode. Signal processors were created and tested that used both between-electrode VCIS channels and a supra-apical virtual channel, which produced the lowest pitch (Dorman et al., 1996; Wilson et al., 1992). A similar concept, that is, a virtual channel with lower pitch than the most apical electrode, is now embodied in the "phantom electrode" system from ABC (Saoji & Litvak, 2010).

### Step 3 and the Fine Structure Processing Strategy

The RTI team, in the early 1990s, created a way to represent the "fine structure" or "fine timing" information in channels with low center frequencies by presenting stimulus pulses at the times of detected peaks or zero crossings in the bandpass filter outputs for the channels (e.g., Wilson et al., 1990a). This approach was called a "peak picker/CIS" strategy, and all channels except the 1–3 channels with the lowest center frequencies presented CIS stimuli.

The peak picker/CIS approach was later refined by the MED-EL GmbH and utilized in its "fine structure processing" (FSP) strategies (e.g., Hochmair et al., 2006).

The processing strategies in current widespread use are shown in Table 1–3. As was the hope of the RTI teams, utilization of discoveries from the NIH projects has been excellent. All of the systems manufactured by the three largest implant companies use a version of the CIS strategy. These versions include the "CIS," "CIS+," "High Definition CIS" (HDCIS), and "Hi-Resolution" (HiRes) strategies, as named by the manufacturers. In addition, (1) the MED-EL and Cochlear systems use various implementations of the *n*-of-*m* approach, including the listed *n*-of-*m*, ACE, and SPEAK strategies; (2) the MED-EL systems use the concept of the peak picker/CIS approach in the FSP strategy; and (3) the AB systems use an implementation of the VCIS approach in their HiRes 120 strategy.

Each of these strategies and others are described in much greater detail in two chapters by Wilson and Dorman, the first on "The design of cochlear implants" (Wilson & Dorman, 2009) and the second on "Signal processing strategies for cochlear implants" (Wilson & Dorman, 2012). The first of these chapters also presents information about other aspects of the design, e.g., design considerations for the electrode array, implanted receiver/stimulator, and transcutaneous transmission link. The second of the chapters is more sharply focused on processing strategies and provides more up-to-date information on that topic. Additional relevant reviews include ones by Loizou (2006), Wilson (2004, 2006), and Zeng et al. (2008).

As of late 2010, more than 220,000 deaf or severely hearing-impaired persons had received CIs, either in one or both ears for each person. The cumulative number of implants over time is shown in Figure 1–2 (adapted and updated from Wilson & Dorman, 2008a). The rapid growth in the number beginning in the early 1990s corresponds to the introductions into standard clinical practice of new and highly effective processing strategies during the early 1990s and afterward.

### Developments in Other Domains

Besides CIS and the other processing strategies mentioned previously, the RTI teams and their collaborating investigators produced or helped to enable advances in many other areas

Table 1-3. Processing Strategies in Current Widespread Use\*

| Manufacturer              | CIS | CIS+ | HDCIS | n-of-m | FSP | ACE | SPEAK | HiRes | HiRes<br>120 |
|---------------------------|-----|------|-------|--------|-----|-----|-------|-------|--------------|
| MED-EL GmbH               | •   | •    | •     | •      | •   |     |       |       |              |
| Cochlear Ltd.             | ٠   |      |       |        |     | •   | •     |       |              |
| Advanced<br>Bionics Corp. | •   |      |       |        |     |     |       | •     | •            |

<sup>\*</sup>Manufacturers are shown in the left column and the processing strategies used in their implant systems are shown in the remaining columns. The full names of the strategies are presented in the text.

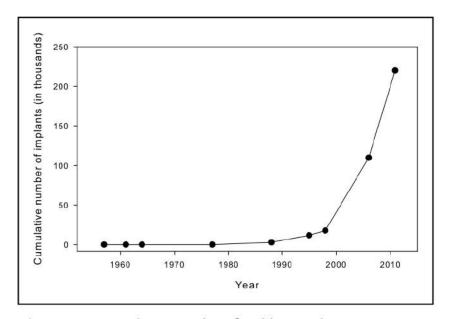


Figure 1–2. Cumulative number of cochlear implants across years. Events marked by the dots include: (1) the first implant operation by Drs. Andre Djourno and Charles Eyriès in 1957; (2) the first two implants by Dr. William F. House in 1961; (3) the first implant by Dr. F. Blair Simmons in 1964; (4) the "Bilger report" in 1977; (5) the first NIH Consensus Conference on Cochlear Implants in 1988; (6) the second NIH Consensus Conference in 1995; (7) the National Academy of Sciences report (Finn et al.) in 1998; (8) an estimate of the cumulative number published in the middle of 2006; and (9) an estimate of the number published in late 2010. Multichannel devices began to supplant single-channel devices in the early 1980s, and highly effective processing strategies were first introduced into widespread clinical use in the early 1990s, as described in the text. These large steps forward fueled the increasing acceptance and applications of cochlear implants. (Adapted with permission from Wilson, B. S., & Dorman, M. F. [2008a]. Interfacing sensors with the nervous system: Lessons from the development and success of the cochlear implant. IEEE Sensors Journal, 8, 131–147. Copyright 2008 IEEE.)

including but not limited to: (1) building of tools for research on CIs such as highly flexible and real-time processing systems; (2) design and application of some of the first portable processors for CIs that were based on digital signal processing and

could support high numbers of processing channels and stimulus sites; (3) development of additional processing strategies for unilateral implants, for example, the "closer mimicking" strategies described in Schatzer et al. (2003) and Wilson et al. (2003, 2006, 2010); (4) evaluation and further development of bilateral CIs and processing strategies for them; (5) evaluation and further development of combined electric and acoustic stimulation of the auditory system for persons with at least some residual hearing at low frequencies; (6) development and application of mathematical models of the electrically stimulated cochlea: (7) recording and interpretation of intracochlear evoked potentials in response to a wide range of electrical stimuli; (8) elucidation of temporal patterns of neural responses in CI patients; (9) evaluation of possible relationships between the temporal patterns and pitch percepts for the same patients; (10) development of processing strategies for the Auditory Brainstem Implant or ABI; (11) psychophysical measures of responses to many different types of electrical stimuli; and (12) design of inexpensive but nonetheless highly effective CI systems primarily for use in low- and mid-income countries.

### Technology Transfer

An important aspect of the work at the RTI was a program of active technology transfer to accelerate or otherwise facilitate the incorporation of inventions and other new concepts or findings into commercially available implant systems. (This program was in addition to the policy on IP described previously; both the program and the policy were designed to facilitate the incorporation of advances into commercially available systems.) We believe this active transfer was far more effective than the alternative passive approach of simply presenting some of the necessary information in publications and the progress reports. We did present the information in those ways, but we also made ourselves available to answer questions and to work directly with the design teams at the manufacturers to move research results into products that people could use. This additional effort was most unusual at the time and in retrospect was an early example of what now is called "translational research" or "translational medicine." The teamwork promoted by the effort was beneficial to all concerned.

Of course, the active technology transfer was only a small fraction of the overall effort needed to produce new or substantially modified CI devices. For that, the companies deserve the greatest credit by far.

### Contributions by Others

Many teams worldwide contributed significantly to the CI systems we have today. The RTI contributions are important, but they are only a part of the story. The fascinating history of CIs is recounted in Eisen (2006, 2009), Finn et al. (1998), Hannaway (1996), Levitt (2008), Niparko and Wilson (2000), Seitz (2002), and Wilson and Dorman (2008b).

One thread that runs through the histories is the remarkable courage and perseverance of the pioneers in laying the foundations for the present devices. Another thread is that no one person or group is primarily responsible for the development of the CI. Many contributions from many sources were needed. For example, different groups contributed most strongly to each of the three major steps listed near the beginning of this chapter.

### SELECTIONS FROM THE NIH PROGRESS REPORTS

Extraordinarily difficult decisions were made in selecting the sections from the NIH progress reports for inclusion in this book. At the outset, we made the easy decision to exclude sections that had been published as journal articles or book chapters, for the reasons mentioned previously. However, that decision did not produce enough of a reduction for a book-length exposition of the projects. We therefore decided to sharpen the focus for the book by excluding all sections from the remaining sections on tool building; portable processors; development of models of the electrically stimulated cochlea; and parametric and longitudinal studies with CIS and other processors. This second (and much more difficult) decision winnowed the list considerably, but did

not shorten it enough. Thus, as a final step we selected what we thought to be the most important sections from among the sections still in the list. The ultimate selections included 20 sections from 18 of the 91 reports.

Guides to the excluded material are presented in Appendices C and D. Appendix C lists the journal articles and book chapters that were published during the projects and also as a result of the projects afterward. Appendix D presents the contents of the RTI progress reports sorted by topic, as opposed to the sorting by project and chronological order in Appendix B. Reference to Appendix D would allow one to identify all reports on any of the many topics, areas, and activities included in the projects.

All of the NIH progress reports are in the public domain and all can be requested from the NIH. In addition, the reports are posted at http://www.rti.org/capr/caprqprs.html, which is a daughter page within the website for the prior Center for Auditory Prosthesis Research at the RTI. This website has been maintained since the closing of the Center in 2008 and may continue to be maintained for the foreseeable future.

In the remainder of this book, the QPRs are referenced by their project number and report number in the format QPR X:Y, where X is the project number (1 through 7; see Table 1–2) and Y is the report number. Similarly, the FRs are referenced by their project number, in the format FR X. The references include: (1) citations to the reports within the text for each chapter, and (2) identification of the report from which the material is drawn for each chapter, in the title and running heading for the chapter.

### NOT A MIRACLE, JUST HARD WORK

In an interview in 1998, a reporter suggested to our long-time research patient Michael Pierschalla (SR2 in the QPRs) that it must seem like a miracle that his hearing had been restored. Michael, remembering the thousands of hours he spent in the laboratory, said quietly, "It is no miracle at all. It is the result of long, long hours of very hard work by researchers around the world." The members of the RTI teams are proud to have been part of that effort and we are grateful to the sponsors, research

20

subjects, administrators, collaborating investigators, and colleagues at companies who made our work possible. The work was exhilarating and among the greatest adventures of our lives.



Michael L. Pierschalla, 1955-2002

This book is dedicated to Michael L. Pierschalla for his unparalleled contributions as a research subject to the development of cochlear implants, and to F. Terry Hambrecht, MD, and William J. Heetderks, MD, PhD, whose informed and inspired leadership of the Neural Prosthesis Program at the NIH led to many important advances in treatments of deafness and other sensory and neurological disorders. These great men played critical roles in making modern cochlear implants possible.

**Sent:** Mon, 13 Oct 2014 18:02:11 -0400 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** FW: Support IRB Barcelona research - please watch and share (English)

Francis, I think you will find this video amusing and fun – and a clever fundraising campaign. I know the Director of the Institute, Joan Guinovart. He is an outstanding scientist (diabetes), very clever and has recruited an amazing (and fun) team in Barcelona. Let me know if you have any interest in visiting the IRB – I know Joan would be thrilled to have you come. M.

# Begin forwarded message:

From: "Joan J. Guinovart" < guinovart@irbbarcelona.org>

**Date:** October 13, 2014 at 9:39:26 AM EDT

To: "Joan J. Guinovart" < joan.guinovart@irbbarcelona.org>

Subject: Fwd: Support IRB Barcelona research - please watch and share (English)

**Reply-To:** <<u>guinovart@irbbarcelona.org</u>>

Dear friend,

I hope you enjoy this dance video, a fundraising initiative.

It is really me in the video!

Best regards

Joan



# http://youtu.be/hNOqgHTtvH8

Scientists at Barcelona's Institute for Research in Biomedicine have been busy learning their dance moves for this video to raise awareness and support for research into diseases such as cancer and metastasis, Alzheimer's and diabetes.

For each YouTube viewing of this video our sponsors will make a donation to IRB Barcelona research. Text IRBBARCELONA to 28014 to contribute €1.20 (Spain only\*).

Direct donations via http://www.irbbarcelona.org/donate

Please watch and share. Together we can find the cures.

\*servicio de SMS solidario operado por Altiria TIC, <u>www.altiria.com</u>, y la Asociación Española de Fundraising, <u>www.aefundraising.org</u>, n°. atn. clte. 902 00 28 98, apdo. correos 36059 - 28080 Madrid; colaboran Movistar, Vodafone, Orange, Yoigo y Euskaltel.

**Sent:** Wed, 3 Jul 2013 06:40:44 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Gretchen

Francis, I wanted to let you know what I am sure you know already - Gretchen is wonderful. I got your note about the SD presentation while I was at our meeting and she was kind enough to print it for me once I got it from my staff. We did not get a chance to review the material but I had it, had we needed it.

It was good to see you - always enjoy that, Maria

**Sent:** Wed, 5 Feb 2014 14:40:51 -0500 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** guidance, please

Francis, Ann Wojcicki has been a member of our Board for a while, albeit not a very active one. She has been selective in her contributions, generously supporting the NHGRI/Smithsonian exhibit celebrating the  $10^{th}$  anniversary of the Genome last year and it is likely she will continue to support the exhibit as it goes to other cities. As you will see from her note below, she is quite interested in AMP – no surprise there – and is asking to speak to someone related to the project. I hesitate to open the doors to the steering committee (or to you, for that matter) but I did not want this request to go unanswered. I realize, of course, there are some hiccups with 23andMe. Should I ask David to speak with her? Would you like to do so? Many thanks, M.

From: Anne Wojcicki [mailto] (b) (6)
Sent: Wednesday, February 05, 2014 2:09 PM

**To:** Freire, Maria (FNIH) [T] **Cc:** Rachel Montana

Subject: Re: IMPORTANT ANNOUNCEMENT

#### Maria

The team at 23andMe has been fascinated about the AMP project and we would love to learn more. Are there steering committee members we could talk to about what their plans are and if and how 23andMe could contribute?

Best, Anne

# On Mon, Feb 3, 2014 at 10:14 PM, Freire, Maria (FNIH) [T] < mfreire@fnih.org > wrote: EMBARGOED UNTIL 10AM EST, FEBRUARY 4, 2014

Dear Members of the FNIH Board,

I am delighted to share with you, on an embargoed basis, the press release announcing the new Accelerated Medicines Partnership (AMP). The formal announcement will be made by Dr. Francis Collins, tomorrow at 10amEST, at The National Press Club, in Washington, DC. You may recall this initiative as the "Target Validation" project, which the Board approved for inclusion in our portfolio in early 2013. Over the past months, FNIH has been actively engaged in planning, organizing and managing the nascent partnership. This could not have been possible without the outstanding leadership and untiring dedication of David Wholley.

In a nutshell, AMP brings together the NIH, 10 companies and several non-profit organizations "to transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets of disease." AMP is being launched with pilot projects in three disease areas: Alzheimer's disease, type 2 diabetes and rheumatoid arthritis/lupus.

The partnership will be managed by FNIH, tapping our considerable expertise in public-private partnerships and alliance management. It is estimated that the partners, through FNIH, will invest approximately \$230million over 5 years.

As is the hallmark of several of our portfolio projects, the data and analysis generated by AMP will be made publicly available to the biomedical community. As such, the AMP activities are precompetitive, with the purpose of increasing research and generating knowledge; the partnership will not engage in or coordinate joint commercial activities between or among its members.

With appreciation for your continued support, Maria

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Spit for Muhammad Ali. Help Parkinson's research.

Anne Wojcicki CEO & Co-Founder, 23andMe

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CEO & Co-Founder, 23andMe

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Spit for Muhammad Ali. Help Parkinson's research.

Anne Wojeicki CEO & Co-Founder, 23andMe (b) (6)

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Spit for Muhammad Ali. Help Parkinson's research.

Anne Wojcicki CEO & Co-Founder, 23andMe

**Sent:** Tue, 22 Oct 2013 10:16:00 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Galien Forum

Francis, I am at the Galien Forum (Chris Austin, Dolsten, Lundberg, Altshuler are also here). I am listening to Elliott Sigal now, very thoughtful. He just 60 6 from BMS. We go back to SNPs, you'll recall. So, question: (b) (4) M.

 Sent:
 Mon, 8 Sep 2014 09:47:30 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Burklow, John (NIH/OD) [E]

Subject: Laskers

Francis, I hope you saw Mary Claire's win for Special Achievement. Peter Walter and Kashutoshi Motion won the Basic Research and Alim Louis Benabid and Mahlon Long won the Clinical award for deep brain stimulation. There has to be NIH funding for some of these. M

**Sent:** Tue, 17 Jun 2014 01:48:30 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E]

Subject: LungMAP launch

Francis, LungMAP officially started yesterday. I am sure you have seen the release from FOCR. We are getting a lot of press attention, which is very good because it will help accrual. As a reminder, we are testing drugs from Amgen, Pfizer, Genentech, AstraZeneca and MedImmune (now part of AZ). Best, M.

 Sent:
 Mon, 22 Jun 2015 21:14:25 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: IOM Commission - your help/inisght

Attachments: Commission SOT\_5 29 15.docx, Commissioner Roster\_6\_4\_15.docx, Draft

Agenda Med Product 6.9.15v1 (2).docx

#### Dear Francis,

As you know, the IOM has established a Commission on "Creating a Global Health Risk Framework for the Future." (Attached are the Statement of Task and the roster of Commission members, all serving in their individual capacity.)

Tachi Yamada and I chair the **Workshop on Research and Development of Medical Products,** one of 4 such workshops that will inform the final report. The draft agenda for the workshop, which will be held in mid-August in Hong Kong, is also attached. Tachi and I are advised on possible speakers by a group of well-known individuals (Peggy Hamburg, Lu Borio, Adel Mahmoud, Patrick Valance, Neil Ferguson, John Rex, and 7 others). Each session will have one or two keynote speakers and a panel of discussants.

I am reaching out to seek your counsel on who should be invited from NIH – <u>an absolutely critical player in the conversation</u>. So far, you, Tony and Cliff Lane have been nominated. Others nominated include, in no particular order:

BT Slingsby, CEO of Global Health Innovative Technologies Fund (GHIT)

Jorge Mestre-Ferrandiz, Office of Health Economics, London

Kevin Outterson, BU Law

Jeremy Farrar, Wellcome Trust

Patrick Vallance, GSK

Rajeev Vankayya, Takeda Vaccines

Manica Balasegaram, MSF Access Campaign

David Reddy, CEO of MMV (formerly VP at Roche)

Krishna Ella, Chairman of Bharat Biotech

Mel Spigelman, TB Alliance

Robin Robinson, BARDA (Also nominated for Session 2 Panel B)

Chris Elias, Bill & Melinda Gates Foundation (Also nominated for Session 5)

Yusuf K. Hamied, Chairman of CIPLA (Also nominated for Session 4 Segment A)

Bernard Pecoul, Drugs for Neglected Diseases (DNDI)

Michael Pfleiderer, Chair, European Medicines Agency

Annick Antierens, Doctors Without Borders (MSF)

Elias Zerhouni, Sanofi

Richard Wilder, BMGF

Nick Cammack, GSK

Anthony So, Duke

Hans-Georg Eichler, EMA

Raymond Chua, HSA

Robert Califf, FDA

Rip Ballou, GSK

Rino Rappuoli, GSK

Moncef Slaoui, GSK

The IOM would like to send out letters of invitation by the end of the week. Your thoughts on who should be invited from NIH would be critically important. While this may be unrealistic, it is my sense is that it would be ideal if you and Tony could attend. I am sending a message to him as well.

Thanks so much, Maria





# GLOBAL HEALTH RISK FRAMEWORK INITIATIVE

# **Commission Roster**

#### Ximena Aguilera, MD

Director

Center of Epidemiology and Public Health Policies Universidad del Desarrollo, Chile

# Irene Akua Agyepong, DrPh, MBChB, FGCPS Greater Accra Regional Health Directorate

Ghana Health Service

# Winnie Byanyima,\* MSc

**Executive Director** Oxfam International

# Alan Davies,\* BBus (Acctey) LLB, LLM, FCA

Chief Executive Officer

Rio Tinto

#### Paul Farmer, MD, PhD

Kolokotrones University Professor and Chair of Department of Global Health and Social Medicine, Harvard Medical School Cofounder of Partners in Health

#### Maria Freire, PhD

President

Foundation for the National Institutes of Health

# Julio Frenk, MD, MPH, PhD

Harvard T.H. Chan School of Public Health

#### Cyvette Gibson

Acting Mayor

City of Paynesville, Liberia

#### Lawrence Gostin, JD

University Professor of Global Health Law Georgetown University Faculty Director

O'Neill Institute on National and Global Law

#### \* Invited

Gabriel Leung, MD, MPH

Dean

Li Ka Shing Faculty of Medicine

Francis Omaswa, MBBCh, MMed, FRCS, FCS

**Executive Director** 

African Center for Global Health and Social Transformation

K. Sujatha Rao, MA, MPA

Former Secretary

Ministry of Health and Family Welfare of India

Daniel Ryan, MA

Head of R&D - Life & Health and Big Data Swiss Re

Peter Sands, MPA

Group Chief Executive Officer Standard Chartered PLC

Oyewale Tomori, DVM, PhD

President

Nigeria Academy of Sciences

Jeanette Vega, MD, MPH, PhD

Director

Chilean National Health Fund

# Suwit Wibulpolprasert, MD

Vice Chair

International Health Policy Program Foundation Health Intervention and Technology Assessment Ministry of Public Health, Thailand

Tachi Yamada, MD

Chief Medical and Scientific Officer Executive Vice President and Board Member Takeda Pharmaceuticals







 Sent:
 Mon, 26 Jan 2015 20:29:45 -0500

 To:
 Collins, Francis (NIH/OD) [E]

Subject: (b) (4)

Francis, (b) (4)

**Sent:** Thu, 28 May 2015 13:22:50 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Tabak, Lawrence

(NIH/OD) [E]

**Subject:** Position Description - FYI and use

Attachments: Operations Director\_Advisor Position.pdf

Dear Francis, Kathy and Larry,

Ann Ashby, who has been the Deputy at FNIH for 7 years, kindly and sadly let me know that she will be leaving at the end of July – she is considering two top-level positions and will take one of them by August. I will miss her enormously but it is time for her to run her own show. Likewise, Andrea Baruchin will be retiring at the end of September, which I knew would happen since I arrived.

These departures give me the chance to restructure the functions and streamline operations. I have decided to combine both roles into one position (attached). Please fill free to circulate the position among those that you think might be a good fit.

As always, many thanks, Maria



#### DIRECTOR OF OPERATIONS/ADVISOR TO THE PRESIDENT

#### NATURE OF WORK

The Director of Operations/Advisor to the President is a role that enables the President and Executive Director of the Foundation to work most effectively with internal and external FNIH stakeholders and fulfill commitments to partners, funders, and the Board of Directors.

#### ESSENTIAL FUNCTIONS

The Director of Operations/Advisor to the President will be responsible for:

- Serving as a critical thought partner to the President and to the FNIH senior staff, while
  providing sound counsel and maintaining confidentiality.
- Staffing the FNIH Board of Directors including preparing materials for all Board and Board committee meetings and supporting specials projects as they arise.
- Supervising the Operations Officer to ensure highly productive and efficient day-to-day functioning of operational initiatives and priorities.
- Supervising the Events team including the Events Manager, Senior Events Coordinator, Events Coordinator and part-time Events Assistant.
- Supervising the Grants, Contracts and Agreements team including the Senior Projects
  Officer and the Senior Grants Manager.
- Supervising a staff employee responsible for preparing the President's slide presentations, talking points, manuscripts and meeting preparation materials.
- Managing human resources including the Foundation's recruitment and applicant tracking, performance and leave management and policies.
- Leading or serving as a team player to support special projects.
- Acting as a point of contact between the President and FNIH employees, NIH staff and partnership stakeholders.
- Representing the FNIH at Foundation for Advanced Education in the Sciences (FAES)
   Board meetings as an ex officio member.
- Serving as the interface to FNIH pro bono legal counsel.

# QUALIFICATIONS

The Director of Operations/Advisor to the President is a facilitative position that requires a combination of focus and flexibility, as well as a willingness to play an active, behind-the-scenes role.

As the President's 'trusted counsel', the job requires a highly resourceful individual with strong emotional intelligence, excellent communication skills, self-motivation, and strong analytical skills. A background in the biomedical field either as an administrator or scientist at the Ph.D. level is highly desired as it will greatly facilitate communicating the work of the Foundation. A candidate also with human resources and administrative management experience would be an excellent complement to the science background. At least 5 years of non-laboratory working experience is required.

The Director of Operations/Advisor to the President must bring to the position maturity, practicality and sensitivity in working with a variety of high-level people at NIH, the FNIH Board of Directors, FNIH staff and contractors, philanthropists and industry, academic and not-for-profit leaders.

#### TO APPLY

Please send an email to <u>resumes@fnih.org</u> with DoO/AP in the subject line. Include your cover letter, resume, and salary requirements.

Sent:Wed, 5 Feb 2014 20:08:44 -0500To:Collins, Francis (NIH/OD) [E]Subject:Re: A great launch for AMP

If she did not mention it, I would just move right along and ignore it. She probably went back and found out of their involvement... Sanofi is not much better. Lana called yesterday and she was chagrined by their internal screw up. Word has it that the head if their AD group did not know the funds had been pulled.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, February 05, 2014 07:52 PM

To: Freire, Maria (FNIH) [T]

Subject: RE: A great launch for AMP

Thanks for the heads up about Peggy – I co-chaired the FDA-NIH Leadership Council with her this afternoon, and she didn't bring this up, so perhaps she is not too deeply miffed.

I have to say --her unawareness of the AMP rollout reflects poorly on FDA internal communications. Janet Woodcock and Sally Howard were intimately aware of the plan. Just the same, I will be ready to apologize if needed.

Best, FC

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, February 05, 2014 2:01 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: A great launch for AMP

I agree. I am glad Sarah got a moment with you; she is a good egg, indeed. I am not convinced there were not some premeditated actions, by the way, but don't think she was the lead or if she could have stopped them.

Heads-up: I saw Peggy this morning at the FDA Advisory Board meeting. She mentioned she had not really known that AMP would be announced yesterday. I apologized for not giving her a heads-up as an ad hoc member of the FNIH Board. I gave my Board the press release, coordinating with Renate and John, so I should have done so. I mentioned, however, that Janet had been invited so I gently put it back on them. I am sure she may have checked on it by now but it would have been nice to let her know. M.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, February 05, 2014 01:36 PM

To: Freire, Maria (FNIH) [T]

Subject: RE: A great launch for AMP

Yes, Sarah was devastated by what happened. I saw her after everyone else had left the Press Club yesterday, and she was in tears. She's a good egg. So is Chase. Michael, on the other hand, has greatly disappointed me.

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, February 05, 2014 6:26 AM

To: Collins, Francis (NIH/OD) [E] Subject: Re: A great launch for AMP

Francis, it WAS a great launch! And you were masterful - in fact, you are featured on our website, video and all. Our Board is delighted we are an integral part of AMP, needless to say. And now, we get to work! As always, all the best, M.

P.S. I had a chance to speak with Sarah about her firm's behavior and let her know very, very clearly how I felt. She knew it had been a huge misstep and was mortified and very apologetic. I took her to John and they spoke for a bit. As to her colleague, I simply froze him out. He burnt a huge bridge.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, February 05, 2014 06:04 AM

To: lon.r.cardon@gsk.com <lon.r.cardon@gsk.com>; Carter, Robert (NIH/NIAMS) [E]; Chin@phrma.org <Chin@phrma.org>; francis.cuss@bms.com <francis.cuss@bms.com>; mikael.dolsten@pfizer.com <mikael.dolsten@pfizer.com>; WHait@ITS.JNJ.COM <WHait@ITS.JNJ.COM>; Hodes, Richard (NIH/NIA) [E]; Insel, Thomas (NIH/NIMH) [E]; Katz, Stephen I. (NIH/NIAMS) [E]; richard.lifton@yale.edu <ri>chard.lifton@yale.edu>; lundberg\_jan@lilly.com <lundberg\_jan@lilly.com>; COyler@its.jnj.com</ri> <COyler@its.jnj.com>; Rodgers, Griffin (NIH/NIDDK) [E]; james.p.sullivan@abbvie.com <james.p.sullivan@abbvie.com>; patrick.5.vallance@gsk.com <patrick.5.vallance@gsk.com>; rupert\_vessey@merck.com <rupert\_vessey@merck.com>; Douq.williams@biogenidec.com <Doug.williams@biogenidec.com>; tachi.yamada@takeda.com <tachi.yamada@takeda.com>; Official <elias.zerhouni@sanofi.com>; Woodcock, Janet (b) (6)>; Wholley, David (b) (6) Hudson, Kathy (NIH/OD) [E]; Cairns-(FNIH) [T]; (b) (6); Freire, Maria (FNIH) [T]; mjmcomer@gmail.com Smith Sarah (b) (6) KDemares@its.jnj.com <KDemares@its.jnj.com>; Jonathan.Zalevsky@takeda.com <Jonathan.Zalevsky@takeda.com>;

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Gary.Nabel@sanofi.com < Gary.Nabel@sanofi.com >; SEchard@rheumatology.org

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<mcarillo@alzheimers.org>; Hanrahan@lupus.org <Hanrahan@lupus.org>

Cc: Burklow, John (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Palisch Chase < (b)(6)

Devaney, Stephanie (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]

Subject: A great launch for AMP

Hello all you AMPeres,

What a wonderful launch event yesterday, with a great turnout! The committed partnership that is AMP really shone through. None of this could have happened without sweat and struggle - we've all spent countless hours over 2 years developing this partnership and working through the details of governance, funding, and the scientific plans. But now the world has heard of our intent to make significant progress

in three disease areas, ultimately promising a leap in our understanding of the biology and the identification of new drug targets.

Monica Langley's story ended up on the front page of the WSJ. In fact, AMP was the most popular story on WSJ.com yesterday afternoon. I've attached a document with a few of the prominent news stories from the last 24 hours.

President Obama also put out a statement on AMP. When I met with him in early January, he mentioned to me that he wanted to AMPlify our new partnership, so this was welcome support: <a href="http://www.whitehouse.gov/the-press-office/2014/02/04/statement-president-accelerated-medicine-partnership">http://www.whitehouse.gov/the-press-office/2014/02/04/statement-president-accelerated-medicine-partnership</a>

Now for the most important part – doing the science. But it will be fascinating and lots of fun to roll up our sleeves together – let's get to work!

With thanks to all and best personal regards,

Francis

**Sent:** Thu, 11 Jul 2013 16:26:43 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: Advice

Hi, Francis. Hmm. I don't think it would be horrendous if you don't show up, especially if this is a truly important opportunity for you to connect with key opinion leaders. Now, having said that, maybe you should ask Al Sommer the question – there may be some interesting winners....

**From:** Collins, Francis (NIH/OD) [E] **Sent:** Thursday, July 11, 2013 3:57 PM

To: Freire, Maria (FNIH) [T]

Subject: Advice

Hi Maria,

Can I ask you to reflect on your former life for a minute?

I just received a personal invitation from two members of the House (one R, one D) to keynote an event focused on childhood cancer. Probably a half dozen members and oodles of staffers. The date? September 20. Yes, that's the day of the Lasker lunch in NYC, which I would have to miss.

I always enjoy the Lasker event and the Pierre Hotel. But at this difficult time, any opportunity to get in front of members of the House and exhort them to release us from sequester is hard to pass up.

How horrendous would it be for me to miss Lasker this year?

FC

**Sent:** Tue, 12 May 2015 14:22:31 -0400

To: Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Hudson, Kathy

(NIH/OD) [E];Burklow, John (NIH/OD) [E]

Subject: OpEd

Attachments: OpEd May 12.docx

Francis, Larry, Kathy and John, FYI, I plan to send this out to coincide with the Award Ceremony next week. Let's see if it gets picked-up, M.

#### DRAFT

#### Young Medical Researchers Face Staggering Odds and Shrinking Job Prospects

#### By Maria Freire

#### 823 Words

Today in the United States 14.8 million adults suffer from major depressive disorders.<sup>1</sup> The number of people ages 65 and older with Alzheimer's is expected to nearly triple from 5.1 million to 13.8 million by 2050.<sup>2</sup> And Parkinson's disease affects more than one million Americans, with 50,000 to 60,000 new cases diagnosed each year.<sup>3</sup>

Stanford University neuroscientist and psychiatrist Dr. Karl Deisseroth is among the brilliant young medical researchers who defy these troubling projections for neurological diseases. At his laboratory in Palo Alto, Deisseroth leads a team that has pioneered the field of optogenetics, which uses light to map the neural circuits in our brains, along with a technology called CLARITY that allows scientists to make organs transparent and thus easier to study under a microscope. These new methodologies make it possible for neuroscientists to develop deeper understandings of Alzheimer's and a multitude of other brain disorders.<sup>4</sup> Now, the efforts of research teams tackling these devastating conditions could produce profound discoveries. At long last, this is an exciting "on-the-verge-of-a-breakthrough" moment that holds great promise for finding cures to intractable disorders.

But at age 43, Deisseroth is an anomaly, as is his laboratory. He has already received multiple accolades and awards<sup>5</sup>, including, on May 20, the prestigious Lurie Prize from t Foundation for the NIH. The Lurie Prize recognizes early-career achievements and, in this instance, recognizes discoveries in the paired use of optogenetics and CLARITY as potential game-changers.

Still, Deisseroth is among a relatively small number of younger researchers who have found sustained funding for their research, in part because of the recognition of his work conferred by his peers and professional organizations including our own. Most of his contemporaries – post-doctoral fellows and primary investigators alike -- toil without recognition and face shrinking job prospects and constant insecurity over research funding. Many decide to leave the field altogether.<sup>6</sup>

Consider this: Despite the fact that the U.S. once was the undisputed leader in biomedical science, support for promising basic research that could yield new treatments for diseases such as diabetes, heart disease and cancer is no longer a top economic priority. Recently, Dr. Francis Collins, Director of the National Institutes of Health, told Bloomberg News, "We've actually lost about 23% of our purchasing power for research over the last twelve years, and that's having a really significant negative effect, particularly on young investigators who are trying to get their labs going." In fact, many of the

<sup>&</sup>lt;sup>1</sup> Nation Institute of Mental Health via American Psychological Association <u>Data on behavioral health in the United States</u>

<sup>&</sup>lt;sup>2</sup> Alzheimer's Association Facts and Figures

<sup>&</sup>lt;sup>3</sup> National Parkinson Foundation, Parkinson's Disease Overview

<sup>&</sup>lt;sup>4</sup> Popular Science, LASER-CONTROLLED AND SEE-THROUGH BRAINS GET BIOMEDICAL PRIZE

<sup>&</sup>lt;sup>5</sup> Deisseroth Lab, Karl Deisseroth, MD, PhD

<sup>&</sup>lt;sup>6</sup> USA Today, Dan Vergano, <u>Science Faces Sequestration Cuts</u>

<sup>&</sup>lt;sup>7</sup> Bloomberg, Medical Research Is Facing a Perfect Storm: Collins

103,100 medical scientists currently working in the U.S.<sup>8</sup> will struggle to hold onto their jobs or advance their careers.<sup>9</sup>

The odds against them are staggering: For every 10 postdoctoral candidates aspiring to a tenure-track professorship within a university, fewer than two will actually succeed. Those who do find jobs face the worst funding environment in 50 years where 85% of research grant proposals submitted are rejected. As a result, the average age a biomedical researcher receives his or her first major grant has risen over the last 20 years to age 45 in 2013. As that age rises, the time apportioned for a scientist to make significant, career-defining discoveries shrinks.

I applaud members of Congress who are supporting significant funding increases to the NIH. As Dr. Collins noted, "If words were votes, things would be looking pretty good right now. There's strong bipartisan support for the idea that it's really been not a good thing to lose momentum, and we ought to try to turn it around." But I wonder, will the aspirational language of the 21st Century Cures Act now in discussion before the House Energy and Commerce Subcommittee be translated into action when it comes time to pass the budget?

Over the last decade, U.S. government support for medical research has been dropping. More recently, we have witnessed the same trend in parts of the private sector. I agree with Dr. Collins when he says, "it's so ironic because scientific opportunities have never been better than they are. The ability to take a vast array of new understandings about the molecular basis of disease and really push forward with new drugs and devices has never been more promising than they are now, but we're cutting back the fuel for the engine." <sup>15</sup>

In the budget negotiations for the new fiscal year, which begins October 1, Congress needs to translate politically popular *pledges* of support into actual (lifesaving) support by approving increased funding levels for the NIH and the Food and Drug Administration (FDA), to ensure that basic research findings are translated into practical uses like medicines, diagnostic and preventive tools and devices for the benefit of all. It is time to reverse the troubling trend of the last 12 years, support our workforce and make good on commitments to promising new research initiatives. Unless Congress adds the fuel, outstanding research scientists in this country will be driving on empty.

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<sup>&</sup>lt;sup>8</sup> US Bureau of Labor Statistics Medical Scientist

<sup>&</sup>lt;sup>9</sup> NPR, Richard Harris, Too Few University Jobs For America's Young Scientists

<sup>&</sup>lt;sup>10</sup> NPR, Richard Harris, <u>Too Few University Jobs For America's Young Scientists</u>

<sup>&</sup>lt;sup>11</sup> Huffington Post, Richard Harris, Congrats Young Scientists, You Face The Worst Research Funding In 50 Years

<sup>&</sup>lt;sup>12</sup> NPR, Richard Harris, Too Few University Jobs For America's Young Scientists

<sup>&</sup>lt;sup>13</sup> NPR, Richard Harris, <u>Too Few University Jobs For America's Young Scientists</u>

<sup>&</sup>lt;sup>13</sup> USA Today, Dan Vergano, Science Faces Sequestration Cuts

<sup>&</sup>lt;sup>14</sup> Baltimore Sun, Funding Young Scientists

<sup>&</sup>lt;sup>14</sup> Bloomberg, Medical Research Is Facing a Perfect Storm: Collins

<sup>&</sup>lt;sup>15</sup> Bloomberg, Medical Research Is Facing a Perfect Storm: Collins

**Sent:** Tue, 26 May 2015 12:51:19 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; McManus, Ayanna

(NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; James, Stephanie (FNIH) [T]

Subject: RE: BMGF-FNIH and today's crunch

Attachments: History of BMGF partnership as of May 2015 (2).doc

Hi Francis – thank you SO much for circling back on this and for the positive consideration. It is truly, truly appreciated!

We keep getting kudos for the award ceremony; it was great fun and we were lucky for the weather. The chemistry between you and Karl was palpable and mesmerizing and everyone loved the song! We have a video of it and some pictures of the event on the website....

Again, thanks to you and your team for your support. All the best, Maria

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, May 26, 2015 12:32 PM

To: Freire, Maria (FNIH) [T]

Cc: Hudson, Kathy (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Wood,

Gretchen (NIH/OD) [E]

Subject: BMGF-FNIH and today's crunch

Hi Maria,

With sincere apologies, we will have to postpone our quarterly meeting for this afternoon – it's total crunch time over here with precision medicine taking over every waking moment (and a lot that should be sleeping).

But Kathy, Larry, and I had a chance to talk this morning about the situation with the two grants involving BMGF and FNIH. While we continue to have some concerns about the Wolbachia/dengue and gene drive/malaria projects, we think your proposal about having BMGF serve as the direct granting agency for the next grant cycle, with Stephanie serving as an expert consultant, should be satisfactory. With respect to the gene drive proposal, we think the NAS study will be very important in considering the benefits and potential ecological risks of release – as it's hard to imagine how such a release could be "limited" in light of the potential for propagation through the species.

(b) (5)

Thanks – will look forward to meeting when this current crunch eases up a bit.

Terrific Lurie Prize event last week!

Francis





**Sent:** Fri, 1 Nov 2013 18:00:04 -0400

To:

'marty@amedconsulting.com'; (b) (6); 'STHIER@PARTNERS.ORG'; 'ssnyder@jhmi.edu'

;Collins, Francis (NIH/OD) [E];'esigal@focr.org'

Cc: 'bchabner@partners.org'

Subject: Re: Boston Red Sox Triumph

Great pictures! Thank you so much, Maria

From: Dr. Martin J. Murphy, Jr. [mailto:marty@amedconsulting.com]

Sent: Friday, November 01, 2013 05:58 PM

To: Dr. Charles A. Sanders (b) (6); Dr. Samuel O. Thier (sthier@partners.org) <sthier@partners.org>; Dr. Solomon H. Snyder (ssnyder@jhmi.edu) <ssnyder@jhmi.edu>; Dr. Solomon H. Snyder (ssnyder@jhmi.edu) <ssnyder@jhmi.edu>; Freire, Maria (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Dr. Ellen V. Sigal (esigal@focr.org) <esigal@focr.org>

Cc: Dr. Bruce A. Chabner (bchabner@partners.org) <bchabner@partners.org>

Subject: Boston Red Sox Triumph

Here is the Boston Red Sox's Honorary Manger (in cap) and his designated hitter Sam Thier!



 $\underline{\text{https://picasaweb.google.com/100208439713835835052/CharlieSandersSamThierAtFNIHBoardMeeting?}} \\ \underline{\text{authuser=0\&authkey=Gv1sRgCN6--rCQ047CDg\&feat=directlink}}$ 

Thanks for a great FNIH board meeting, Charlie and Maria!

# Marty

Martin J. Murphy, DMedSc, PhD, FASCO Chairman & Chief Executive Officer AlphaMed Consulting, Inc.
P: +919.402.8750 (office)
C: (b) (6) (cell)

F: +919.402.9799 (fax)

E: Marty@AMedConsulting.com

 Sent:
 Thu, 9 Apr 2015 11:43:23 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

 Subject:
 RE:

#### CONFIDENTIAL

Francis,

(b) (4) (b) (4) M.

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, April 08, 2015 7:32 AM

To: Freire, Maria (FNIH) [T]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: (b) (4

Hi Maria,



**Francis** 

**Sent:** Thu, 11 Jul 2013 16:31:53 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: Advice

Glad your ability to read between the lines is still the best! Smiling, M.

From: Collins, Francis (NIH/OD) [E] Sent: Thursday, July 11, 2013 4:31 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: Advice

Thanks!

From: Freire, Maria (FNIH) [T]

**Sent:** Thursday, July 11, 2013 4:27 PM **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: Advice

Hi, Francis. Hmm. I don't think it would be horrendous if you don't show up, especially if this is a truly important opportunity for you to connect with key opinion leaders. Now, having said that, maybe you should ask Al Sommer the question – there may be some interesting winners....

**From:** Collins, Francis (NIH/OD) [E] **Sent:** Thursday, July 11, 2013 3:57 PM

To: Freire, Maria (FNIH) [T]

Subject: Advice

Hi Maria,

Can I ask you to reflect on your former life for a minute?

I just received a personal invitation from two members of the House (one R, one D) to keynote an event focused on childhood cancer. Probably a half dozen members and oodles of staffers. The date? September 20. Yes, that's the day of the Lasker lunch in NYC, which I would have to miss.

I always enjoy the Lasker event and the Pierre Hotel. But at this difficult time, any opportunity to get in front of members of the House and exhort them to release us from sequester is hard to pass up.

How horrendous would it be for me to miss Lasker this year?

FC

 From:
 Freire, Maria (FNIH) [T]

 Sent:
 Sat, 18 Jul 2015 10:53:53 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: RE: Catching up

(b) (6)

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, July 18, 2015 10:53 AM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: Catching up

(b) (6)

From: Freire, Maria (FNIH) [T]

**Sent:** Saturday, July 18, 2015 9:11 AM **To:** Collins, Francis (NIH/OD) [E] **Subject:** FW: Catching up

Francis, FYI from John Porter.

(b) (6) Best, Maria

From: Porter, John E. [mailto:john.porter@hoganlovells.com]

**Sent:** Friday, July 17, 2015 10:45 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** Re: Catching up

I may be late with it. (b) (6)

Sent from my iPhone

On Jul 16, 2015, at 11:06 PM, "Freire, Maria (FNIH) [T]" (b) (6) wrote:

Dear John,

(b) (6)

As you know, Ann Ashby will be leaving us at the end of the month. We are compiling a scrap book as a surprise for her with notes from people with whom she worked while she was here and, of course, you came to mind. Would you be willing to write a note to be included in the book? I know she would love that! If you decide to do se, we would need it by the middle of next week – we can print it for you if you send the letter, if this is easier for you.

Please do let us know if we can be of help. All the best, Maria

# **About Hogan Lovells**

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 Sent:
 Sun, 2 Jun 2013 17:55:42 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: RE: (b) (6)

| (b) (6 |
|--------|
|        |
|        |
|        |

From: Collins, Francis (NIH/OD) [E] Sent: Sunday, June 02, 2013 5:54 PM

To: Freire, Maria (FNIH) [T]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: RE: David's son

Thanks for passing this on, Maria. (b) (6)

Francis

From: Freire, Maria (FNIH) [T] Sent: Sunday, June 02, 2013 5:51 PM

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: (b) (6)

Dear Francis and Kathy,





**Sent:** Fri, 13 Mar 2015 05:39:57 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E];McManus, Ayanna (NIH/OD) [E];Wood, Gretchen

(NIH/OD) [E]

Subject: RE: Deisseroth

OH, THANK YOU!!! Yes, it will be great fun! Woohoo!!!

**From:** Collins, Francis (NIH/OD) [E] **Sent:** Friday, March 13, 2015 5:39 AM

To: Freire, Maria (FNIH) [T]

Cc: Hudson, Kathy (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

Subject: RE: Deisseroth

Sounds like fun, I'd be glad to do this!

Best, Francis

From: Freire, Maria (FNIH) [T]

**Sent:** Friday, March 13, 2015 5:24 AM **To:** Collins, Francis (NIH/OD) [E] **Cc:** Hudson, Kathy (NIH/OD) [E]

Subject: Deisseroth

Hi, Francis. I missed our meeting this week, which luckily will be in a few days. During our discussion, I was going to ask you (on bended knee) if you would be willing to take an active role in the FNIH Award ceremony on May  $20^{th}$  with a conversation, on stage, with Karl. The two of you together would be dynamite; the audience will be absolutely mesmerized. Ann Lurie and Sol Snyder are so keen on the idea that they personally wrote you the formal invitation letter (included here). Please, please say yes! M.

 Sent:
 Wed, 8 Apr 2015 07:39:07 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

 Subject:
 Re: (b) (4)

Hi, Francis. (b) (4)

Thank you!

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, April 8, 2015 7:32 AM

To: Freire, Maria (FNIH) [T]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: (b) (4)

Hi Maria,

(b) (4)

**Francis** 

From: Freire, Maria (FNIH) [T] Sent: Thu, 9 Apr 2015 12:04:05 -0400 To: Collins, Francis (NIH/OD) [E] Cc: Hudson, Kathy (NIH/OD) [E] Subject: RE (b) (4) (b) (4) thanks! From: Collins, Francis (NIH/OD) [E] Sent: Thursday, April 09, 2015 12:03 PM To: Freire, Maria (FNIH) [T] Cc: Hudson, Kathy (NIH/OD) [E] Subject: RE: (b)(4)

(b) (4)

From: Freire, Maria (FNIH) [T]

Sent: Thursday, April 09, 2015 11:43 AM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Hudson, Kathy (NIH/OD) [E]

Subject: RE: (b) (4)

CONFIDENTIAL

Francis,

(b) (4) (b) (4) M.

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, April 08, 2015 7:32 AM

To: Freire, Maria (FNIH) [T]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: (b) (4)

Hi Maria,

(b) (4)



Francis

**Sent:** Wed, 6 Nov 2013 09:12:08 -0500 **To:** Tabak, Lawrence (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E];Gray, Felicia (FNIH) [T]

Subject: Re: FNIH as an approved award giver

Hi, Larry - let me look into the Lurie issue; it is a bit surprising to me. I need to make sure we fix it going forward.

However, it would also be good to discuss other potential awards. By copy of this e-mail I am asking Felicia to work with your staff to set something up.

As always, many thanks for your help. All the best, Maria

---- Original Message ----

From: Tabak, Lawrence (NIH/OD) [E] Sent: Tuesday, November 05, 2013 10:44 AM

To: Freire, Maria (FNIH) [T]

Cc: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: RE: FNIH as an approved award giver

#### Maria,

I need clarification please, since as you know from your days on the Awards subcommittee of the ACD, NIH places awards, not organizations, on the pre-cleared list. Many organizations have several awards that have been individually cleared. And each award needs its own written criteria in order for it to be cleared.

As you know, at present, NIH employees cannot be nominated for one FNIH award (the Lurie Prize). We asked FNIH in 2012 to create the needed set of written standards. But unfortunately that has not occurred. If you are considering a policy change in this area, Holli and I are available to discuss this with you, if that would be helpful.

Best wishes,

Larry

----Original Message----

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, November 05, 2013 6:59 AM

To: Tabak, Lawrence (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: FNIH as an approved award giver

Dear Larry,

I hope this finds you well and digging successfully from under the furlough e-mail mountain. I come to respectfully request that FNIH be reviewed to attain approval and be placed on the list of awards that have been cleared by NIH ethics review - ideally at the next ACD meeting.

The reason for the request, apart from the logical merit, is that such designation would have enormous impact on our ability to swiftly address pressing NIH needs, provide incentives or otherwise support NIH employees in their duties.

We could envision, for example, a travel award for a postdoc or a new PI to attend a meeting or conference, once he/she has been cleared to do so. The awards, in all likelihood, would be relatively small since we do not have excess resources we can tap, but they could transform the NIH experience for a scientist early in his/her career.

Having been one of the two members of the ACD that reviewed awards, I am well aware of the importance of being on the approved list and know that such a designation will serve NIH well because it would allow FNIH to exercise the authorities Congress provided in its authorizing legislation.

I am happy to chat about this further at your earliest convenience. All the best, Maria

**Sent:** Fri, 25 Oct 2013 06:07:14 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: FNIH Board

Of course, Francis, I understand very well. Sooo, any chance for a big announcement about our budget (had to ask!). See you soon, Maria

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, October 25, 2013 06:01 AM

To: Freire, Maria (FNIH) [T] Subject: FNIH Board

Hi Maria,

I have a rather complicated day on October 31. Will it be a problem if I miss the morning meeting and just turn up for the noon -1 PM section? I plan to attend the dinner on Oct. 30 and can do lots of schmoozing then.

Sound OK?

Francis

**Sent:** Tue, 22 Oct 2013 10:23:30 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Galien Forum

(b) (4)

M.

---- Original Message -----

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, October 22, 2013 10:19 AM

To: Freire, Maria (FNIH) [T] Subject: RE: Galien Forum

(b) (4)

----Original Message----From: Freire, Maria (FNIH) [T]

Sent: Tuesday, October 22, 2013 10:16 AM

To: Collins, Francis (NIH/OD) [E]

Subject: Galien Forum

Francis, I am at the Galien Forum (Chris Austin, Dolsten, Lundberg, Altshuler are also here). I am listening to Elliott Sigal now, very thoughtful. He just retired from BMS. We go back to SNPs, you'll recall. So, question:

(b) (4) M.

**Sent:** Tue, 22 Oct 2013 10:34:45 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Galien Forum

You and TVC just got a nice shout out from Lundberg! Big thanks to him. He said he was hoping to have an announcement later this year, BTW.

---- Original Message -----

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, October 22, 2013 10:19 AM

To: Freire, Maria (FNIH) [T] Subject: RE: Galien Forum

(b) (4)

-----Original Message-----

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, October 22, 2013 10:16 AM

To: Collins, Francis (NIH/OD) [E]

Subject: Galien Forum

Francis, I am at the Galien Forum (Chris Austin, Dolsten, Lundberg, Altshuler are also here). I am listening to Eiliott Sigal now, very thoughtful. He just retired from BMS. We go back to SNPs, you'll recall. So, question:

(b) (4) M.

**Sent:** Mon, 25 Nov 2013 13:20:18 -0500

To: Hudson, Kathy (NIH/OD) [E];Collins, Francis (NIH/OD) [E]

Subject: RE: FDA to 23andMe: Stop Selling Kits Immediately

Good – see you tomorrow. BTW – Ann is an FNIH Board member (not very active but she did contribute to the Smithsonian exhibit). M.

From: Hudson, Kathy (NIH/OD) [E]

Sent: Monday, November 25, 2013 1:19 PM

To: Freire, Maria (FNIH) [T]; Collins, Francis (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E]

Subject: RE: FDA to 23andMe: Stop Selling Kits Immediately

Yes, we had it. thanks

From: Freire, Maria (FNIH) [T]

Sent: Monday, November 25, 2013 1:18 PM

To: Collins, Francis (NIH/OD) [E]

**Cc:** Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E] **Subject:** FDA to 23andMe: Stop Selling Kits Immediately

Francis, in case you have not seen this, from BIO-IT World. M.

**November 25, 2013** | The Food and Drug Administration issued a <u>warning letter</u> to 23andMe CEO Ann Wojcicki on Friday, saying the company was selling its spit kits and Personal Genome Service without marketing clearance or approval in violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act).

The direct-to-consumer personalized genomics test is "intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease," FDA contends, citing language on the 23andMe website heralding the service as the "first step in prevention".

FDA specifically highlighted concerns about 23andMe's assessment for BRCA-related genetic risk and drug responses. "For instance," FDA wrote, "if the BRCA-related risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist."

These are not new criticisms. The BRCA concerns, in particular, have been raised by many including Ellen Matloff, Director of the Cancer Genetic Counseling Center at Yale Cancer Center, at the <u>Consumer Genetics Conference in September</u>.

The FDA's letter exudes frustration, pointing out issues that 23andMe had "failed to address... during previous interactions with the Agency," saying further: "Since July of 2009, we have been diligently working to help you comply with regulatory requirements... However, even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses."

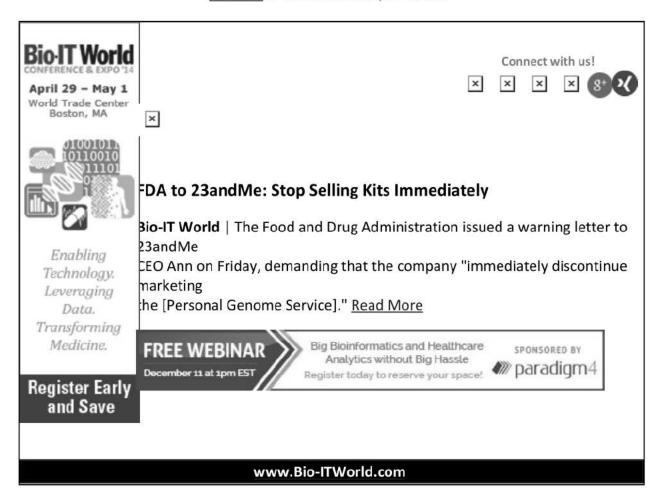
The letter states that FDA has not received any correspondence from 23andMe since May. That month, speaking at the <u>Big Data in Biomedicine conference</u> at Stanford University, Wojcicki announced that the company had dropped the price of genotyping to \$99 in hopes of getting one million customers by the end of the year and enable "really truly disruptive" research. In August, the company launched a <u>television marketing campaign</u>.

"We have become aware that you have initiated new marketing campaigns, including television commercials that, together with an increasing list of indications, show that you plan to expand the PGS's uses and consumer base without obtaining marketing authorization from FDA," the FDA's letter said.

The regulatory body's directive is clear: "23andMe must immediately discontinue marketing the PGS until such time as it receives FDA marketing authorization for the device."

At the time of writing, kits were still for sale on the 23andMe site.

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From: Freire, Maria (NIH/OD) [E]

Sent: Thu, 1 Nov 2012 19:31:40 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: RE: First day on the job...

That is SO kind, Francis. We would love that when it works for you guys. In the meantime, onward and upward!

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, November 01, 2012 6:58 PM

**To:** Freire, Maria (NIH/OD) [E] **Subject:** RE: First day on the job...

Hey there Maria,

Woo hoo!! It's great that you are really on board. And yes, I am ready and willing to do battle on whatever fronts are needed to make the NIH-FNIH partnership a roaring success!

Diane and I would really like to have you and your husband come to our place for a welcoming dinner with a few other folks. Life is crazy, so it may take a little while to make the schedule work, but I'll get back to you about possible dates.

All best, Francis

From: Freire, Maria (NIH/OD) [E]

Sent: Thursday, November 01, 2012 6:48 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** First day on the job...

Hi, Francis! I feel like the kid that just started school – excited and nervous but very happy. Just wanted to say hello – I will take you up on your request/promise that we have standing meetings to catch up. Much to discuss and plan. All my best, always, M.

P.S. You will notice I show up as an NIH employee – thanks to being on the ACD!!! Interesting...

Sent:Sun, 2 Jun 2013 17:57:29 -0400To:Collins, Francis (NIH/OD) [E]Subject:RE: Grieving with you

Thanks, Francis. (b) (6)

From: Collins, Francis (NIH/OD) [E] Sent: Sunday, June 02, 2013 5:56 PM

To: Wholley, David (FNIH) [T]
Cc: Freire, Maria (FNIH) [T]
Subject: Grieving with you

Dear David,

(b) (6)

Francis

 Sent:
 Thu, 6 Feb 2014 07:16:48 -0500

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Re: guidance, please

Perfect. Thank you, Francis.

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, February 06, 2014 06:08 AM

**To**: Freire, Maria (FNIH) [T] **Subject**: RE: guidance, please

Hi Maria,

Thanks for asking. I know Ann W pretty well — we have had lots of talks over the years about personalized medicine. But I think David would be the right person to talk with her about AMP. I'm not sure I can immediately see a connection between the AMP projects and 23andMe.

FC

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, February 05, 2014 2:41 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** guidance, please

Francis, Ann Wojcicki has been a member of our Board for a while, albeit not a very active one. She has been selective in her contributions, generously supporting the NHGRI/Smithsonian exhibit celebrating the  $10^{th}$  anniversary of the Genome last year and it is likely she will continue to support the exhibit as it goes to other cities. As you will see from her note below, she is quite interested in AMP – no surprise there – and is asking to speak to someone related to the project. I hesitate to open the doors to the steering committee (or to you, for that matter) but I did not want this request to go unanswered. I realize, of course, there are some hiccups with 23andMe. Should I ask David to speak with her? Would you like to do so? Many thanks, M.

From: Anne Wojcicki [mailto (b) (6) Sent: Wednesday, February 05, 2014 2:09 PM

To: Freire, Maria (FNIH) [T]

Cc: Rachel Montana

Subject: Re: IMPORTANT ANNOUNCEMENT

Maria

The team at 23andMe has been fascinated about the AMP project and we would love to learn more. Are there steering committee members we could talk to about what their plans are and if and how 23andMe could contribute?

Best,

#### Anne

# On Mon, Feb 3, 2014 at 10:14 PM, Freire, Maria (FNIH) [T] < mfreire@fnih.org > wrote: EMBARGOED UNTIL 10AM EST, FEBRUARY 4, 2014

Dear Members of the FNIH Board,

I am delighted to share with you, on an embargoed basis, the press release announcing the new Accelerated Medicines Partnership (AMP). The formal announcement will be made by Dr. Francis Collins, tomorrow at 10amEST, at The National Press Club, in Washington, DC. You may recall this initiative as the "Target Validation" project, which the Board approved for inclusion in our portfolio in early 2013. Over the past months, FNIH has been actively engaged in planning, organizing and managing the nascent partnership. This could not have been possible without the outstanding leadership and untiring dedication of David Wholley.

In a nutshell, AMP brings together the NIH, 10 companies and several non-profit organizations "to transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets of disease." AMP is being launched with pilot projects in three disease areas: Alzheimer's disease, type 2 diabetes and rheumatoid arthritis/lupus.

The partnership will be managed by FNIH, tapping our considerable expertise in public-private partnerships and alliance management. It is estimated that the partners, through FNIH, will invest approximately \$230million over 5 years.

As is the hallmark of several of our portfolio projects, the data and analysis generated by AMP will be made publicly available to the biomedical community. As such, the AMP activities are precompetitive, with the purpose of increasing research and generating knowledge; the partnership will not engage in or coordinate joint commercial activities between or among its members.

With appreciation for your continued support, Maria

--

Spit for Muhammad Ali. Help Parkinson's research.

Anne Wojcicki CEO & Co-Founder, 23andMe --

Spit for Muhammad Ali. Help Parkinson's research.

Anne Wojcicki CEO & Co-Founder, 23andMe

(b) (6)

--

Spit for Muhammad Ali, Help Parkinson's research.

Anne Wojcicki CEO & Co-Founder, 23andMe

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Spit for Muhammad Ali. Help Parkinson's research.

Anne Wojcicki CEO & Co-Founder, 23andMe

(b) (6)

\_\_

Spit for Muhammad Ali. Help Parkinson's research.

Anne Wojcicki

 Sent:
 Mon, 22 Jun 2015 21:39:32 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: RE: IOM Commission - your help/inisght

Thanks, Francis. Yes, I know Mike and Roger. Let me see what Tony says. Best, M.

From: Collins, Francis (NIH/OD) [E] Sent: Monday, June 22, 2015 9:37 PM

**To:** Freire, Maria (FNIH) [T] **Cc:** Hudson, Kathy (NIH/OD) [E]

Subject: RE: IOM Commission - your help/inisght

Hi Maria,

Thanks for your note. For NIH, I won't be able to make it to Hong Kong, but perhaps Tony or Cliff can go. If neither of them can, Mike Kurilla of NIAID would be good. The other person to invite would be Roger Glass, the head of the Fogarty International Center, and the Associate NIH Director for Global Health.

Best, Francis

From: Freire, Maria (FNIH) [T]

**Sent:** Monday, June 22, 2015 9:14 PM **To:** Collins, Francis (NIH/OD) [E] **Cc:** Hudson, Kathy (NIH/OD) [E]

Subject: IOM Commission - your help/inisght

Dear Francis,

As you know, the IOM has established a Commission on "Creating a Global Health Risk Framework for the Future." (Attached are the Statement of Task and the roster of Commission members, all serving in their individual capacity.)

Tachi Yamada and I chair the **Workshop on Research and Development of Medical Products,** one of 4 such workshops that will inform the final report. The draft agenda for the workshop, which will be held in mid-August in Hong Kong, is also attached. Tachi and I are advised on possible speakers by a group of well-known individuals (Peggy Hamburg, Lu Borio, Adel Mahmoud, Patrick Valance, Neil Ferguson, John Rex, and 7 others). Each session will have one or two keynote speakers and a panel of discussants.

I am reaching out to seek your counsel on who should be invited from NIH – <u>an absolutely critical player in the conversation</u>. So far, you, Tony and Cliff Lane have been nominated. Others nominated include, in no particular order:

**BT Slingsby**, CEO of Global Health Innovative Technologies Fund (GHIT) **Jorge Mestre-Ferrandiz**, Office of Health Economics, London **Kevin Outterson**, BU Law Jeremy Farrar, Wellcome Trust

Patrick Vallance, GSK

Rajeev Vankayya, Takeda Vaccines

Manica Balasegaram, MSF Access Campaign

David Reddy, CEO of MMV (formerly VP at Roche)

Krishna Ella, Chairman of Bharat Biotech

Mel Spigelman, TB Alliance

**Robin Robinson**, BARDA (Also nominated for Session 2 Panel B)

Chris Elias, Bill & Melinda Gates Foundation (Also nominated for Session 5)

Yusuf K. Hamied, Chairman of CIPLA (Also nominated for Session 4 Segment A)

Bernard Pecoul, Drugs for Neglected Diseases (DNDI)

Michael Pfleiderer, Chair, European Medicines Agency

Annick Antierens, Doctors Without Borders (MSF)

Elias Zerhouni, Sanofi

Richard Wilder, BMGF

Nick Cammack, GSK

Anthony So, Duke

Hans-Georg Eichler, EMA

Raymond Chua, HSA

Robert Califf, FDA

Rip Ballou, GSK

Rino Rappuoli, GSK

Moncef Slaoui, GSK

<u>The IOM would like to send out letters of invitation by the end of the week</u>. Your thoughts on who should be invited from NIH would be critically important. While this may be unrealistic, it is my sense is that it would be ideal if you and Tony could attend. I am sending a message to him as well.

Thanks so much, Maria

**Sent:** Mon, 22 Jun 2015 21:42:02 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: IOM Commission - your help/inisght

P.S. They will probably want to invite you anyway, so don't be surprised. M.

**From:** Collins, Francis (NIH/OD) [E] **Sent:** Monday, June 22, 2015 9:37 PM

**To:** Freire, Maria (FNIH) [T] **Cc:** Hudson, Kathy (NIH/OD) [E]

Subject: RE: IOM Commission - your help/inisght

Hi Maria,

Thanks for your note. For NIH, I won't be able to make it to Hong Kong, but perhaps Tony or Cliff can go. If neither of them can, Mike Kurilla of NIAID would be good. The other person to invite would be Roger Glass, the head of the Fogarty International Center, and the Associate NIH Director for Global Health.

Best, Francis

From: Freire, Maria (FNIH) [T]

**Sent:** Monday, June 22, 2015 9:14 PM **To:** Collins, Francis (NIH/OD) [E] **Cc:** Hudson, Kathy (NIH/OD) [E]

Subject: IOM Commission - your help/inisght

Dear Francis,

As you know, the IOM has established a Commission on "Creating a Global Health Risk Framework for the Future." (Attached are the Statement of Task and the roster of Commission members, all serving in their individual capacity.)

Tachi Yamada and I chair the **Workshop on Research and Development of Medical Products,** one of 4 such workshops that will inform the final report. The draft agenda for the workshop, which will be held in mid-August in Hong Kong, is also attached. Tachi and I are advised on possible speakers by a group of well-known individuals (Peggy Hamburg, Lu Borio, Adel Mahmoud, Patrick Valance, Neil Ferguson, John Rex, and 7 others). Each session will have one or two keynote speakers and a panel of discussants.

I am reaching out to seek your counsel on who should be invited from NIH – <u>an absolutely critical player in the conversation</u>. So far, you, Tony and Cliff Lane have been nominated. Others nominated include, in no particular order:

BT Slingsby, CEO of Global Health Innovative Technologies Fund (GHIT)
Jorge Mestre-Ferrandiz, Office of Health Economics, London
Kevin Outterson, BU Law
Jeremy Farrar, Wellcome Trust

Patrick Vallance, GSK Rajeev Vankayya, Takeda Vaccines Manica Balasegaram, MSF Access Campaign David Reddy, CEO of MMV (formerly VP at Roche) Krishna Ella, Chairman of Bharat Biotech Mel Spigelman, TB Alliance Robin Robinson, BARDA (Also nominated for Session 2 Panel B) Chris Elias, Bill & Melinda Gates Foundation (Also nominated for Session 5) Yusuf K. Hamied, Chairman of CIPLA (Also nominated for Session 4 Segment A) Bernard Pecoul, Drugs for Neglected Diseases (DNDI) Michael Pfleiderer, Chair, European Medicines Agency Annick Antierens, Doctors Without Borders (MSF) Elias Zerhouni, Sanofi Richard Wilder, BMGF Nick Cammack, GSK Anthony So, Duke Hans-Georg Eichler, EMA

Rip Ballou, GSK

Raymond Chua, HSA Robert Califf, FDA

Rino Rappuoli, GSK

Moncef Slaoui, GSK

The IOM would like to send out letters of invitation by the end of the week. Your thoughts on who should be invited from NIH would be critically important. While this may be unrealistic, it is my sense is that it would be ideal if you and Tony could attend. I am sending a message to him as well.

Thanks so much, Maria

 Sent:
 Mon, 8 Sep 2014 09:54:45 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Burklow, John (NIH/OD) [E]

Subject: Re: Laskers

Ugh, hate auto-correct. It is Mori not Motion, if course and DeLong not Long.

From: Freire, Maria (FNIH) [T]

Sent: Monday, September 8, 2014 9:47 AM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Burklow, John (NIH/OD) [E]

Subject: Laskers

Francis, I hope you saw Mary Claire's win for Special Achievement. Peter Walter and Kashutoshi Motion won the Basic Research and Alim Louis Benabid and Mahlon Long won the Clinical award for deep brain stimulation. There has to be NIH funding for some of these. M

**Sent:** Tue, 22 Oct 2013 17:11:27 -0400

To: Burklow, John (NIH/OD) [E];Collins, Francis (NIH/OD) [E];Tabak, Lawrence

(NIH/OD) [E];Hudson, Kathy (NIH/OD) [E];Barros, Colleen (NIH/OD) [E];White, Pat (NIH/OD)

[E]; Jorgenson, Lyric (NIH/OD) [E]; Devaney, Stephanie (NIH/OD) [E]

Cc: Landis, Story (NIH/NINDS) [E]; Kutlak, Frank (NIH/OD/ORF) [E]; Mowery, Tara

(NIH/OD) [E]

**Subject:** Re: Good news...nobody showed up.

Teamwork! Works every time. A special thanks to Story and Frank. Maria

From: Burklow, John (NIH/OD) [E]

**Sent**: Tuesday, October 22, 2013 05:04 PM

**To**: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Barros, Colleen (NIH/OD) [E]; White, Pat (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]; Devaney, Stephanie

(NIH/OD) [E]; Freire, Maria (FNIH) [T]

Cc: Landis, Story (NIH/NINDS) [E]; Kutlak, Frank (NIH/OD/ORF) [E]; Mowery, Tara (NIH/OD) [E];

Burklow, John (NIH/OD) [E]

**Subject**: Good news...nobody showed up.

Good news! I understand that nobody showed up for the dedication today. I also understand that Dr. Landis and Frank Kutlak stayed at the building with Tara for an hour, just in case. Thank you!

John

### John Burklow

Associate Director for Communications and Public Liaison National Institutes of Health Building 1, Room 344 (301) 496-4461 (phone) (301) 496-0017 (fax) burklowj@od.nih.gov



Celebration of Science at NIH: watch how medical research saves lives and improves health

**Sent:** Sun, 13 Oct 2013 14:41:51 -0400 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** Re: got a minute?

I do, indeed. I am open now and all day tomorrow, except between and 6pm. My cell is

(b) (6)

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, October 13, 2013 02:21 PM

**To**: Freire, Maria (FNIH) [T] **Subject**: got a minute?

Hi Maria,

Do you have 5-10 minutes today or tomorrow for a phone call?

(b) (5)

Let me know; I'm pretty flexible except for a conference call from 5 – 6 PM today and hoping to go out to see "Gravity" after 7 PM. Tomorrow (Columbus Day) is wide open.

FC

 Sent:
 Fri, 17 Jul 2015 17:01:07 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Subject:
 RE: Note for Ann Ashby

Perfect!

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, July 17, 2015 3:05 PM
To: Freire, Maria (FNIH) [T]
Subject: RE: Note for Ann Ashby

Corrected version attached. Thanks.

#### Dear Ann:

I want to thank you for all that you've done over the years on behalf of NIH in your role at the Foundation. I know you've always worked tirelessly behind the scenes to ensure that all things FNIH go flawlessly—most recently, the Lurie Prize event, which was fabulous. My deep appreciation for all your contributions and best wishes as you begin your new adventure!

Best,

Francis

From: Freire, Maria (FNIH) [T]
Sent: Friday, July 17, 2015 10:44 AM
To: Collins, Francis (NIH/OD) [E]
Subject: Re: Note for Ann Ashby

Lovely! Except she is not retiring. She is considering a couple of options right now; just taking her time to decide what she'd like to do. She could retire, actually, but not ready just yet.

**From:** Collins, Francis (NIH/OD) [E] **Sent:** Friday, July 17, 2015 9:31 AM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: Note for Ann Ashby

Hi Maria,

I am happy to supply a note for the scrap book. How about this?

#### Dear Ann:

Congratulations on your retirement! I want to thank you for all that you've done over the years on behalf of NIH in your role at the Foundation. I know you've always worked tirelessly behind the scenes to ensure that all things FNIH go flawlessly—most recently, the Lurie Prize event, which was fabulous. My deep appreciation for all your contributions and best wishes as you begin your new adventure!

Best,

Francis

From: Freire, Maria (FNIH) [T]
Sent: Monday, July 13, 2015 9:48 AM
To: Collins, Francis (NIH/OD) [E]
Subject: Note for Ann Ashby

Dear Francis,

As you know, Ann Ashby will be leaving at the end of July. We are compiling a scrap book as a surprise for her with notes from people she cherished and respected while here. Would you be willing to write a note to be included in the book? I know she would love that! If it is easier, just send it electronically by next Monday so we can print it out and include it in the book.

Also, we will be having a small farewell for her at the FNIH offices the afternoon of July 30<sup>th</sup>. Your schedule is crazy, I know, but it would be lovely if you could join us. I'll send you the electronic invitation. M.

Sent:Thu, 28 May 2015 10:48:19 -0400To:Collins, Francis (NIH/OD) [E]Subject:RE: Note from Charlie Sanders

Thanks for copying me, Francis. I did not know he had written – good for Charlie. Steve Paul also told me he had some very kind, moving words for him. Best, M.

(b) (6)

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, May 28, 2015 10:45 AM

To: Lori Franklin

Cc: Freire, Maria (FNIH) [T]

Subject: RE: Note from Charlie Sanders

Thanks, Charlie, for your wonderful note – it was great to see you. This year's Lurie Prize event was indeed terrific.

Best, Francis

From: Lori Franklin [mailto: (b) (6)

Sent: Thursday, May 28, 2015 10:10 AM To: Collins, Francis (NIH/OD) [E] Subject: Note from Charlie Sanders

# Dear Francis:

Your presence at the FNIH dinner really made the difference for the evening. The interview with Karl made oculo-genetics understandable which is hard to do. And after your performance on the guitar of "Bright Sunshiny Day" I think you ought to go on the road! In any event thank you for all your continuing support of the FNIH. I hope we are doing everything we possibly can to serve the interest of the NIH because that is our goal.

Best wishes.

Charlie

-

# Lori Franklin

Assistant to the Sanders Family

(b)(6)

Cell: (b) (6)

**Sent:** Sun, 14 Jul 2013 19:33:34 -0400

To: Collins, Francis (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Hudson, Kathy

(NIH/OD) [E]

Subject: RE: Prospectus regarding Mary Lasker and Florence Mahoney

Hi, Francis.

# (b) (5), M.

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, July 14, 2013 12:40 PM

To: Burklow, John (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Freire, Maria (FNIH) [T]

Subject: Prospectus regarding Mary Lasker and Florence Mahoney

Hi John, Kathy, and Maria,

Lee Rosenberg asked me to look at a brief prospectus form Richard Cohen (formerly a producer for such icons as Walter Cronkite) and Bradie Metheny on a proposed web video featuring Mary Lasker and Florence Mahoney. A rather sketchy outline is attached. There is no budget mentioned, but it's clear that Richard and Bradie are looking for some kind of financial support.

(b) (5)

FC

**Sent:** Mon, 20 May 2013 08:38:28 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: NEJM Perspective on Nurturing Clinician-Scientists at the NIH

Thanks, Francis. This will be very, very helpful. I am pleased to tell you that we got a new pledge for 2 new MRSP fellows at our Board meeting in Chicago. Onward and upward! M.

From: Collins, Francis (NIH/OD) [E] Sent: Thursday, May 16, 2013 12:51 PM

To: Freire, Maria (FNIH) [T]

Subject: FW: NEJM Perspective on Nurturing Clinician-Scientists at the NIH

From: Gottesman, Michael (NIH/OD) [E] Sent: Thursday, May 16, 2013 10:13 AM

To: List NIHSD-L; IC

Cc: Ognibene, Fred (NIH/CC/OD) [E]; Baum, Bruce (NIH/CC/OD) [C]; McBurney, Margaret (NIH/OD) [E];

Kleinman, Joe (NIH/OD) [E]

Subject: NEJM Perspective on Nurturing Clinician-Scientists at the NIH

The attached perspective on "The Role of the NIH in Nurturing Clinical-Scientists" appeared in yesterday's NEJM. We hope this will bring some attention to our three new programs: the NIH-Lasker Clinical Research Scholars Program, Opportunities for Collaborative Research at the NIH Clinical Center, and the Medical Research Scholars Program. My thanks to all of you who made these programs possible and will make them successful.

Michael

 Sent:
 Fri, 17 Jul 2015 10:43:49 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Subject:
 Re: Note for Ann Ashby

Lovely! Except she is not retiring. She is considering a couple of options right now; just taking her time to decide what she'd like to do. She could retire, actually, but not ready just yet.

From: Collins, Francis (NIH/OD) [E] Sent: Friday, July 17, 2015 9:31 AM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: Note for Ann Ashby

Hi Maria,

I am happy to supply a note for the scrap book. How about this?

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

#### Dear Ann:

Congratulations on your retirement! I want to thank you for all that you've done over the years on behalf of NIH in your role at the Foundation. I know you've always worked tirelessly behind the scenes to ensure that all things FNIH go flawlessly—most recently, the Lurie Prize event, which was fabulous. My deep appreciation for all your contributions and best wishes as you begin your new adventure!

Best.

Francis

From: Freire, Maria (FNIH) [T]
Sent: Monday, July 13, 2015 9:48 AM
To: Collins, Francis (NIH/OD) [E]
Subject: Note for Ann Ashby

Dear Francis,

As you know, Ann Ashby will be leaving at the end of July. We are compiling a scrap book as a surprise for her with notes from people she cherished and respected while here. Would you be willing to write a note to be included in the book? I know she would love that! If it is easier, just send it electronically by next Monday so we can print it out and include it in the book.

Also, we will be having a small farewell for her at the FNIH offices the afternoon of July 30<sup>th</sup>. Your schedule is crazy, I know, but it would be lovely if you could join us. I'll send you the electronic invitation. M.

 From:
 Freire, Maria (NIH/OD) [E]

 Sent:
 Sat, 22 Dec 2012 21:42:39 -0500

 To:
 Collins, Francis (NIH/OD) [E]

Subject: RE: Thank you!

Hi, Francis! I cannot tell you how happy I am to be home - and by home I mean, of course, Ernesto and Maryland and I also mean dear friends and colleagues that are like family. I am well aware it is due, in no small measure, to you. Thank you! And thank you especially for extending such a warm personal welcome - it is truly moving. Merry Christmas and the very best for 2013! M.

----Original Message----

From: Collins, Francis (NIH/OD) [E] Sent: Saturday, December 22, 2012 7:10 PM

To: Freire, Maria (NIH/OD) [E]

Cc: Diane Baker

Subject: RE: Thank you!

Hi Maria,

Thanks for your nice note -- it was our pleasure to serve as the conveners for such a delightful evening. As just one example of the response, Tony Fauci told me the next day that he had enjoyed the dinner immensely, and is thrilled to have you as our leader at FNIH. I agree!

Like Diane, I am embarrassed that we totally neglected to thank you for the beautiful arrangement of lilies. They were right there on the little table in the window of the kitchen, and everyone benefitted from their beauty and fragrance -- but we forgot to say where they came from.

I hope you and Ernesto have a wonderful holiday, and let us all look forward to changing the world for the better in 2013.

Best, Francis

----Original Message----

From: Diane Baker [mailto] (b) (6) Sent: Saturday, December 22, 2012 11:00 AM

To: Freire, Maria (NIH/OD) [E] Cc: Collins, Francis (NIH/OD) [E]

Subject: Re: Thank you!

#### Dear Maria,

Thank you for you note! Your mother would also be appalled at my lack of manners in not thanking you for the beautiful bouquet of lilies that share their festive fragrance with us as I write. When they arrived Thursday I found just the right place for them and then totally forgot to thank you in person! so, a belated thanks for your foresight and scented thoughtfulness. Francis and I love an evening like Thursday - wonderful people gathered sharing ideas and laughter.

(b) (6)

Hugs and welcome back home!

Diane & Francis

(b) (b)

```
On Fri, Dec 21, 2012 at 4:08 PM, Freire, Maria (NIH/OD) [E] <mfreire@fnih.org> wrote:
> Dear Diane and Francis,
>
> I take this expedited route to send you my heartfelt thanks for the
> lovely, lovely dinner last night. My mother would be appalled I am
> not sending you a proper note, but I am afraid you will not receive it
> until you are back from visiting family and this could not wait that long!
>
> The evening was just magical - everyone was warm and welcoming and I
> felt much affection and support. Needless to say, this was only
> possible because you opened your home and your hearts - it is a memory I will carry forever.
>
                                                                            (b) (6)
> With great appreciation and affection, Maria
>
>
```

From: Freire, Maria (NIH/OD) [E] Sat, 22 Dec 2012 21:30:08 -0500 Sent:

To: 'Diane Baker'

Cc: Collins, Francis (NIH/OD) [E]

RE: Thank you! Subject:

Dear Diane.

(b) (6)

I am very glad you received the flowers and that they are nicely fragrant. And speaking of flowers, Francis went over and above the call of duty when he brought out the orchid in the rain!

Have a wonderful, wonderful I visit with family. I look forward to seeing you in the New Year. Big hug back to you! Maria

----Original Message----

From: Diane Baker [mailto: (b) (6) Sent: Saturday, December 22, 2012 11:00 AM

To: Freire, Maria (NIH/OD) [E] Cc: Collins, Francis (NIH/OD) [E]

Subject: Re: Thank you!

Dear Maria.

Thank you for you note! Your mother would also be appalled at my lack of manners in not thanking you for the beautiful bouquet of lilies that share their festive fragrance with us as I write. When they arrived Thursday I found just the right place for them and then totally forgot to thank you in person! so, a belated thanks for your foresight and scented thoughtfulness. Francis and I love an evening like Thursday - wonderful people gathered sharing ideas and laughter.

(b)(6)

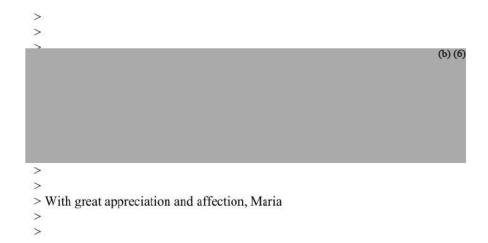
Hugs and welcome back home!

Diane & Francis

(b)(6)

On Fri, Dec 21, 2012 at 4:08 PM, Freire, Maria (NIH/OD) [E] <mfreire@fnih.org> wrote:

- > Dear Diane and Francis,
- >
- > I take this expedited route to send you my heartfelt thanks for the
- > lovely, lovely dinner last night. My mother would be appalled I am
- > not sending you a proper note, but I am afraid you will not receive it
- > until you are back from visiting family and this could not wait that long!
- >
- > The evening was just magical everyone was warm and welcoming and I
- > felt much affection and support. Needless to say, this was only
- > possible because you opened your home and your hearts it is a memory I will carry forever.



 Sent:
 Fri, 1 Nov 2013 06:14:22 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: Re: Thank you!

Good plan. See you guys soon. Kathy, we missed you at dinner. Francis galvanized the room - it was great! M.

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, October 31, 2013 08:42 PM

To: Freire, Maria (FNIH) [T]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: RE: Thank you!

Hi Maria,

It was great to meet with the Board; the chemistry and energy seems quite good. (Hopefully the philanthropy is too!)

I think November 26 will be OK, we'll shout if we need to meet sooner.

Best, Francis

From: Freire, Maria (FNIH) [T]

Sent: Thursday, October 31, 2013 5:51 PM

To: Collins, Francis (NIH/OD) [E]

Subject: Thank you!

Hi, Francis – thank you for coming last night and today. Everyone was extremely happy that you made the time to come and are enthusiastic about moving forward together. Paul Montrone (I've attached his bio) will come with me to Thermo-Fisher and Joel Marcus is already on the job, as you know. You and I are scheduled to meet on November 26<sup>th</sup> but if you think we should move up the conversation, please let me know. With appreciation, M.

**Sent:** Wed, 19 Feb 2014 10:13:53 -0500 **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: Today

You made me laugh - I'll bring an army, then....

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, February 19, 2014 10:12 AM

To: Hudson, Kathy (NIH/OD) [E]; Freire, Maria (FNIH) [T]

Cc: Devaney, Stephanie (NIH/OD) [E]; Wholley, David (FNIH) [T]

Subject: RE: Today

The more the merrier.

From: Hudson, Kathy (NIH/OD) [E]

Sent: Wednesday, February 19, 2014 9:57 AM

To: Freire, Maria (FNIH) [T]

Cc: Collins, Francis (NIH/OD) [E]; Devaney, Stephanie (NIH/OD) [E]; Wholley, David (FNIH) [T]

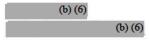
Subject: Re: Today

That is fine Maria!

Kathy Hudson, Ph.D.

Deputy Director for Science, Outreach, and Policy

NIH



On Feb 19, 2014, at 9:48 AM, "Freire, Maria (FNIH) [T]" < mfreire@fnih.org > wrote:

Hi, Francis and Kathy. I had my weekly update with David yesterday and he mentioned the topics of the meeting with you today. Since it will include staffing, IP and other issues on which I can be helpful, it will be good for both of us to be there. See you in a bit, M.

Sent: Tue, 18 Jun 2013 14:31:44 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: RE: Sequestration Blues

I know! BTW, I'd like to tell you about Paul Herrling's offer vis-à-vis BRAIN. My sense is it you be good for you to spend a few minutes with him and do the statesman thing. M.

----Original Message----

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, June 18, 2013 12:38 PM

To: Freire, Maria (FNIH) [T] Cc: Burklow, John (NIH/OD) [E] Subject: RE: Sequestration Blues

Ha! I sang another version of the Sequester Blues at the NIH Directors' awards last week. You gotta laugh or you'll cry.

FC

----Original Message----

From: Freire, Maria (FNIH) [T] Sent: Tuesday, June 18, 2013 9:51 AM To: Collins, Francis (NIH/OD) [E] Cc: Burklow, John (NIH/OD) [E] Subject: Sequestration Blues

Francis - you are developing a fan club. People are tweeting and re-sending your video to list-servs. Going viral, my friend... Your next gig - Nashville? Smiling, M.

Sent:Tue, 18 Jun 2013 15:09:32 -0400To:Collins, Francis (NIH/OD) [E]Subject:RE: Sequestration Blues

Anytime. I can call you - it will take about 3 min or you can call me at your convenience

(b) (6)

----Original Message----

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, June 18, 2013 2:56 PM

To: Freire, Maria (FNIH) [T] Subject: RE: Sequestration Blues

Sure, I'd be glad to hear about this...

----Original Message----

From: Freire, Maria (FNIH) [T] Sent: Tuesday, June 18, 2013 2:32 PM To: Collins, Francis (NIH/OD) [E] Subject: RE: Sequestration Blues

I know! BTW, I'd like to tell you about Paul Herrling's offer vis-à-vis BRAIN. My sense is it you be good for you to spend a few minutes with him and do the statesman thing. M.

----Original Message----

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, June 18, 2013 12:38 PM

To: Freire, Maria (FNIH) [T] Cc: Burklow, John (NIH/OD) [E] Subject: RE: Sequestration Blues

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FC

----Original Message----

From: Freire, Maria (FNIH) [T] Sent: Tuesday, June 18, 2013 9:51 AM To: Collins, Francis (NIH/OD) [E] Ce: Burklow, John (NIH/OD) [E] Subject: Sequestration Blues

Francis - you are developing a fan club. People are tweeting and re-sending your video to list-servs. Going viral, my friend... Your next gig - Nashville? Smiling, M.

Sent: Wed, 15 May 2013 11:59:14 -0400

To: Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E];Burklow, John (NIH/OD) [E]

Subject: Re: THANK YOU!

Terrific - we'll do that!

---- Original Message -----

From: Collins, Francis (NIH/OD) [E] Sent: Wednesday, May 15, 2013 11:58 AM

To: Freire, Maria (FNIH) [T]

Cc: Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: RE: THANK YOU!

Posting on YouTube should be OK -- but it will be important to post the entire film, not just the song. Otherwise the references in the song won't make sense.

FC

----Original Message----

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, May 15, 2013 8:19 AM

To: Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: THANK YOU!

Francis - a couple of movie producers may be calling. You were a HIT. Your song, quite simply, made the evening. You have everyone smiling and clapping. Thank you for the bottom of my heart!

More seriously, I've had about 10 people asking for the video. Including Ann Lurie's significant other, who is a movie producer. He wants to put it on YouTube. Of course, I've not given it to anyone.... Thoughts?

You are the BEST! M.

 Sent:
 Tue, 18 Jun 2013 09:51:05 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Burklow, John (NIH/OD) [E]

Subject: Sequestration Blues

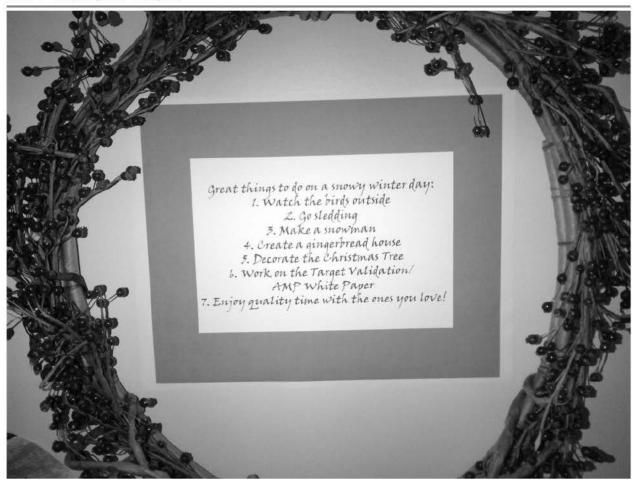
Francis - you are developing a fan club. People are tweeting and re-sending your video to list-servs. Going viral, my friend... Your next gig - Nashville? Smiling, M.

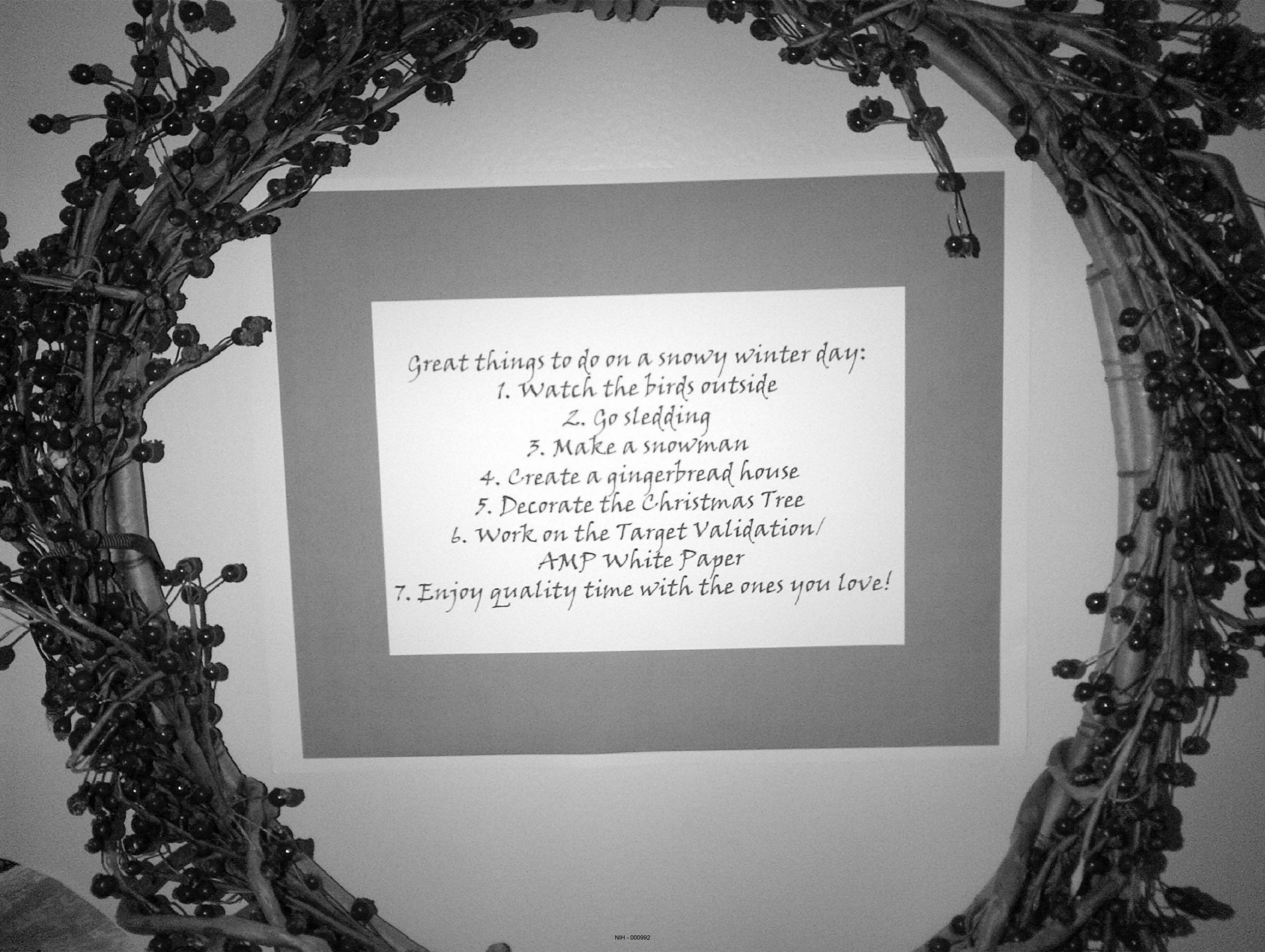
**Sent:** Tue, 17 Dec 2013 17:37:46 -0500

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: Talk about commitment!
Attachments: IMG-20131217-00193.jpg

Francis/Kathy – we have a door decorating contest at FNIH. Here is Maria Vasileva's door motif. See item 6 - Ho, Ho, Ho! Best, M.





**Sent:** Wed, 15 May 2013 08:18:58 -0400

To: Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E];Burklow, John (NIH/OD) [E]

Subject: THANK YOU!

Francis - a couple of movie producers may be calling. You were a HIT. Your song, quite simply, made the evening. You have everyone smiling and clapping. Thank you for the bottom of my heart!

More seriously, I've had about 10 people asking for the video. Including Ann Lurie's significant other, who is a movie producer. He wants to put it on YouTube. Of course, I've not given it to anyone.... Thoughts?

You are the BEST! M.

From: Freire, Maria (NIH/OD) [E] Sent: Fri, 21 Dec 2012 16:08:01 -0500 To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc:

Thank you! Subject:

Dear Diane and Francis,

I take this expedited route to send you my heartfelt thanks for the lovely, lovely dinner last night. My mother would be appalled I am not sending you a proper note, but I am afraid you will not receive it until you are back from visiting family and this could not wait that long!

The evening was just magical - everyone was warm and welcoming and I felt much affection and support. Needless to say, this was only possible because you opened your home and your hearts - it is a memory I will carry forever.



With great appreciation and affection, Maria

**Sent:** Thu, 31 Oct 2013 17:50:59 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Thank you!

Attachments: Paul Montrone BIO.docx

Hi, Francis – thank you for coming last night and today. Everyone was extremely happy that you made the time to come and are enthusiastic about moving forward together. Paul Montrone (I've attached his bio) will come with me to Thermo-Fisher and Joel Marcus is already on the job, as you know. You and I are scheduled to meet on November 26<sup>th</sup> but if you think we should move up the conversation, please let me know. With appreciation, M.

#### Paul Montrone BIO

For more than three decades, Paul M. Montrone directed the development of a number of businesses in a diverse set of industries. In addition to his positions in the public companies indicated below, his other business interests have been conducted through Latona Associates, a private management and investment company with ownership of various manufacturing and service enterprises.

Dr. Montrone was the CEO of Fisher Scientific International Inc. from its initial public offering in 1991 until its merger with Thermo Electron in 2006, forming Thermo Fisher Scientific Inc. Under Dr. Montrone's leadership, Fisher was transformed from a North American manufacturer and distributor into a global enterprise supplying research, testing and clinical laboratories in 150 countries with over 600,000 products and services. Annual sales increased from \$760 million in 1991 to approximately \$6.0 billion in 2006. Over this period, the equity value of Fisher increased from approximately \$200 million to \$12 billion and the annual return to shareholders was 26% compounded.

Prior to leading Fisher Scientific, Dr. Montrone was the Chairman and CEO of Wheelabrator Technologies Inc., a leading environmental services company that is now a wholly owned subsidiary of Waste Management, Inc. Annual shareholder returns at Wheelabrator under his leadership were 22% compounded.

Previously, Dr. Montrone was Executive Vice President of The Signal Companies, Inc. and its successor, AlliedSignal Inc. (now Honeywell International Inc.), as well as President of The Henley Group, Inc. and Executive Vice President and CFO of Wheelabrator-Frye Inc.

Dr. Montrone began his career at the Pentagon, serving in the Systems Analysis Group in the Office of Secretary of Defense Robert McNamara while a Captain in the U.S. Army. A helicopter pilot, he is now President of the New England Helicopter Council.

For many years, Dr. Montrone also participated in healthcare policy matters at the national level. During the Clinton Administration, he was a member of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, as well as a founder of the National Forum for Health Care Quality Measurement and Reporting. He was a Director of The Healthcare Leadership Council and the New England Healthcare Institute, a member of the Health and Retirement Task Force of the Business Roundtable, and is currently a Director and Treasurer of the Foundation for the National Institutes of Health.

He is also involved in Washington, DC business policy matters, principally through his activity with the Business Roundtable, as a member of its Planning Committee, and Chairman of the Civil Justice Reform Taskforce, and as a member of the President's Advisory Group of the U.S. Chamber of Commerce.

He has served on a number of corporate boards and has also been active in many not for profit institutions, especially The Metropolitan Opera, where he has served in various capacities over three decades including President and CEO. He is now President Emeritus. In addition, he is currently on the boards of the New England Conservatory, the Boston Symphony Orchestra, and the Columbia University Graduate School of Business.

Born in Scranton, Pa., in 1941, Dr. Montrone graduated magna cum laude from the University of Scranton in 1962 and holds a Ph.D. from Columbia University.

Sent: Thu, 9 Apr 2015 12:03:17 -0400

To: Hudson, Kathy (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E]

Subject: RE: white house citation

Woohoo!!! Will do!

From: Hudson, Kathy (NIH/OD) [E] Sent: Thursday, April 09, 2015 11:56 AM

To: Freire, Maria (FNIH) [T]
Cc: Collins, Francis (NIH/OD) [E]
Subject: white house citation

Got a positive response. They want a draft. I asked for model but haven't gotten yet but you might see if you can find anything related floating on the web and go ahead and ask your staff to start drafting. Apparently getting it done once they have the draft takes a while so we should not dilly dally.

Kathy L. Hudson, Ph.D.
Deputy Director for Science, Outreach, and Policy
National Institutes of Health

(b) (6)



**Sent:** Wed, 21 May 2014 05:42:39 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E]

Subject: Re: wow!

And you were sorely missed, Francis! We will make sure we can get you to join us next year.

Yes, Brazil is fascinating, indeed. I hope you saw Carlos Morel; he is fabulous.

Safe travels, M.

From: Collins, Francis (NIH/OD) [E] Sent: Wednesday, May 21, 2014 05:27 AM

To: Hudson, Kathy (NIH/OD) [E]; Freire, Maria (FNIH) [T]

Cc: Burklow, John (NIH/OD) [E]

Subject: RE: wow!

Wow, indeed! What an amazing evening, Maria – you really know how to create a fabulous experience.

So sorry to have missed the event this year because of my trip to Brazil. Fascinating country, by the way.

Best, Francis

From: Hudson, Kathy (NIH/OD) [E] Sent: Tuesday, May 20, 2014 10:40 PM

To: Freire, Maria (FNIH) [T]

Cc: Collins, Francis (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: wow!

Maria,

This evening's Lurie prize dinner was nothing short of fantastic! Right people, right atmosphere, right size, all terrific. Loved my table company.

(b) (6)

Small world of those of us with discerning taste and class!

Thanks for letting me make off with the Erlenmeyer flash.

With love and appreciation for all you and the foundation do for us,  $\ensuremath{\mathsf{Kathy}}$ 

**Sent:** Sun, 9 Nov 2014 10:30:09 -0500 **To:** Hudson, Kathy (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E];Burklow, John (NIH/OD) [E]

Subject: RE: Wyeth and the Connectome

Yup, I agree.

From: Hudson, Kathy (NIH/OD) [E]

Sent: Sunday, November 09, 2014 10:25 AM

To: Freire, Maria (FNIH) [T]

Cc: Collins, Francis (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: Re: Wyeth and the Connectome

Maria

We have had some discussions about this internally.

(b) (5)

Kathy Hudson, Ph.D.

Deputy Director for Science, Outreach, and Policy

NIH

(b) (6)

On Nov 9, 2014, at 9:57 AM, "Freire, Maria (FNIH) [T]"

(b) (6) wrote:

Hi, Francis.

(b) (4)

Wyeth's interest in FNIH came about because they supported an NIH nutrition workshop last fall; they liked what they saw and approached us about other projects dealing with early childhoodevelopment. When I mentioned the possibility, you suggested I reach out to Alan, Tom and Story, which I did. They all agreed that the Lifespan Connectome would be an ideal project. In a nutshell:

- The Lifespan Connectome has been divided into three age ranges: 0-4, 4-21, and 45 and older.
- For the 4-21 and 45+ age groups, the existing data collection protocols can be used to obtain data comparable to the data in the current HCP project.
- However, the 0-4 age range presents a data collection challenge because of the limited number of research groups that are sufficiently experienced collecting data from toddlers, and the difficulty in working with those subjects makes the experiments more expensive.

 Given the anticipated level of NIH funding available for the Lifespan Connectome, it is not clear that there are sufficient funds to support robust data collection in that age range.

So, the funding from Wyeth would support data collection in the 0-4 age range.

If we are successful in getting the funds, NIH would prepare and release a special program announcement seeking grant applications for study of this age range. Applications would be reviewed using the NIH peer review system and funded through typical funding mechanisms. FYI, we are working very closely with Greg Farber (NIMH) and Lisa Freund (NICHD) to outline exactly what the funding would support.

| As you can imagine, this is very exciting and positive. | (b) (4)<br>(b) (4) |
|---------------------------------------------------------|--------------------|
|                                                         |                    |
|                                                         |                    |

There is no action item for you here, just an FYI. Best, M.

**Sent:** Mon, 11 Nov 2013 10:01:38 -0500 **To:** Collins, Francis (NIH/OD) [E]

Cc: Hodes, Richard (NIH/NIA) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: Re: Your November 1 meeting with the Longevity Dividend Group

Thanks for the heads-up Francis. We'll see what they have to say.

It is very common for folks to tell us there are "big bucks out there" for their pet project - the reality, as you know, is very different.

(b) (4)

(b) (4)

(b) (4) (I meet with him tomorrow - you'll know whose head

it is you see rolling down Rockville Pike...).

It occurs to me, making all due apologies for my ignorance on what they will have to say and going only on their letter, that we may be able to kick this one to a global stage. Specifically, I am one of 60 people that Ban Ki-moon has gathered to work on the post-millennium development goals - remember them? The health goal, one of 10, is about healthy living and aging (and universal health coverage). No money specifically, as these things go, but perhaps a way to put this issue on the map. We'll see...

I will be meeting with Richard and his senior staff soon, so I will get his views on this directly. Best, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Monday, November 11, 2013 09:16 AM

To: Freire, Maria (FNIH) [T]

Cc: Hodes, Richard (NIH/NIA) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: FW: Your November 1 meeting with the Longevity Dividend Group

Hi Maria,

I met with this group last week to hear about their vision for a "Longevity Dividend Initiative". Most of what they are proposing is a natural extension of the research agenda of NIA. I let them know that their ideas of having this launched as a Presidential Grand Challenge were not likely to go anywhere. Still, they seem convinced that there are big bucks out there just waiting to be harvested. They may come looking for you....

Francis

**From:** George M. Martin [mailto:gmmartin@uw.edu]

Sent: Friday, November 08, 2013 3:06 AM

To: Collins, Francis (NIH/OD) [E]

**Cc:** sjayo@uic.edu; brian.kennedy@buckinstitute.org; James L. Kirkland, MD,PhD - Mayo Clinic (kirkland.james@mayo.edu); James Appleby (jappleby@geron.org); Stephanie Lederman (stephanie@afar.org); Hodes, Richard (NIH/NIA) [E]; Sierra, Felipe (NIH/NIA) [E]

Subject: Your November 1 meeting with the Longevity Dividend Group

Subject: Tour November 1 meeting with the Longevity Dividend Group

#### Dear Francis,

My colleagues and I were delighted to have had the opportunity to discuss the current stage of development of the "Longevity Dividend Initiative" with you last week. The attached letter, a collective work of several of your visitors at that meeting, summarizes what we learned from that discussion and includes some suggestions for your consideration.

Warm regards, George

George M. Martin, M.D.
Professor of Pathology Emeritus
K-543 Health Sciences Building
Department of Pathology BOX 357470
University of Washington
1959 NE Pacific Street
Seattle, WA 98195-7470
Tel 206 543 5088 Fax 206 685 8356
Mobile (b) (6)
gmmartin@uw.edu

Sent: Thu, 30 Oct 2014 16:20:40 -0400

To: Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E]

Subject: With enormous appreciation

Dear Francis,

I cannot tell you what it means for the Foundation and especially for me, to have gotten such wonderful news this morning. Sol, who was next to me, gave me a big hug and is was all I could do not to burst into tears. I am not sure you got to hear the spontaneous applause and I know you did not see the smiles – too bad because it was truly memorable.

A highlight came when Steve Mayer, our treasurer, was going over the budget. With a twinkle in his eye he said: (b) (4)

(b) (4)' It was great fun, as it was to see the energy that was generated in the room. The money is critical, but the signal of support that you sent means the world to the Board – thank you!

And, of course, I am indebted to Kathy, who navigated the process with so much care and purpose. Thank you, thank you, and thank you!

We will make you proud, Maria

Sent: Sun, 9 Nov 2014 09:57:44 -0500
To: Collins, Francis (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: Wyeth and the Connectome

Hi, Francis.



Wyeth's interest in FNIH came about because they supported an NIH nutrition workshop last fall; they liked what they saw and approached us about other projects dealing with early childhoodevelopment. When I mentioned the possibility, you suggested I reach out to Alan, Tom and Story, which I did. They all agreed that the Lifespan Connectome would be an ideal project. In a nutshell:

- The Lifespan Connectome has been divided into three age ranges: 0-4, 4-21, and 45 and older.
- For the 4-21 and 45+ age groups, the existing data collection protocols can be used to obtain data comparable to the data in the current HCP project.
- However, the 0-4 age range presents a data collection challenge because of the limited number of research groups that are sufficiently experienced collecting data from toddlers, and the difficulty in working with those subjects makes the experiments more expensive.
- Given the anticipated level of NIH funding available for the Lifespan Connectome, it is not clear that there are sufficient funds to support robust data collection in that age range.

So, the funding from Wyeth would support data collection in the 0-4 age range.

If we are successful in getting the funds, NIH would prepare and release a special program announcement seeking grant applications for study of this age range. Applications would be reviewed using the NIH peer review system and funded through typical funding mechanisms. FYI, we are working very closely with Greg Farber (NIMH) and Lisa Freund (NICHD) to outline exactly what the funding would support.

| As you can imagine, this is very exciting and positive. | (b) (4)<br>(b) (4) |
|---------------------------------------------------------|--------------------|
|                                                         |                    |
|                                                         |                    |

There is no action item for you here, just an FYI. Best, M.

**Sent:** Fri, 8 May 2015 10:45:04 -0400 **To:** Hudson, Kathy (NIH/OD) [E]

Cc: Wolinetz, Carrie (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence

(NIH/OD) [E]; James, Stephanie (FNIH) [T]

Subject: VCTR Grant Transition Plan
Attachments: 2015 Transition Plan draft.doc

Hi Kathy,

As you know, following your request that we not move forward with the renewal of the VCTR grant, we have been in direct and extensive contact with the Gates Foundation to sort out a path forward. We all agree that the science and the potential positive benefit to eradicate malaria makes this a very important endeavor. FNIH is cognizant, however, of NIH's sensitivities and we want to be responsive to the agency and responsible to our funder.

(b) (5)

Of course, I will have to get formal approval from my Board for this proposal; I am confident that they will be amenable. Please let me know as soon as possible if this addresses NIH's concerns so that I can let Chris and the other Gates folks know. They must be ready to pick up the funding once this one expires so there is no funding hiatus for the PIs.

Best, M.







**Sent:** Thu, 25 Apr 2013 10:40:49 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E]
Subject: and on the good news front....

#### CONFIDENTIAL

Francis, Kathy – as I mentioned at our last meeting, we have been working with the Geoffrey Beene folks on a Challenge prize to "ask solvers to identify male/female differences in early cognitive decline, to promote earlier interventions for both women and men" - well, mostly women, really. We plan to send out a press release on the 30<sup>th</sup> of April, but the first announcement of the challenge and the release of a video will happen the evening before, April 29<sup>th</sup>, at the Society for Women's Health Research (SWHR) annual gala dinner in DC. John Burklow has been great in helping us with this – as always!

Also, and again confidentially, it appears that an OpEd piece that Meryl Comer and I submitted to the New York Times may have been accepted – woohoow!!! In it we highlight the disproportionate burden of AD on women and the importance of NIA/NIH's investment in ADNI. We are told the editors are working on it – I'll keep you posted. Best, M.

**Sent:** Thu, 4 Apr 2013 17:28:14 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: McManus, Ayanna (NIH/OD) [E];Gray, Felicia (FNIH) [T];Ashby, Ann (FNIH) [T]

Subject: FNIH Board meeting invitation
Attachments: Dr. Collins Board Mtg Invitation.pdf

Dear Francis,

As I mentioned earlier, we have changed the FNIH Board meeting to the morning of May 15<sup>th</sup> in Chicago; the formal letter of invitation is attached. Your presence at these meetings is of enormous importance because you provide the Board with a clear sense of NIH's direction and goals how FNIH can contribute to accomplishing them. We will send the logistical information under a separate cover. I sincerely hope you can join us.

All the best, Maria



April 4, 2013

Dr. Francis Collins

Director

National Institutes of Health

1 Center Drive, Room 126

Bethesda, MD 20892-0148

Dear Dr. Collins

The Board of Directors of the Foundation for the National Institutes of Health (FNIH), of which you are an ex officio Member, will hold its Annual Meeting the morning of May 15, 2013 in Chicago. Please note that this is a change of date and venue; the meeting had been scheduled to be on May 22, 2013 at a local hotel.

The reason for the change is that we have decided to coordinate this meeting with the FNIH Award ceremony that will take place on May 14th, in Chicago in which we will bestow the Lurie Prize to Ruslan M. Medzhitov. The FNIH Award ceremony is part of our strategic plan to enhance support for the Medical Research Scholars Program (MRSP), a program that we know is among the top priorities of the National Institutes of the Health (NIH). Your active participation at the ceremony by delivering the keynote address is critical to this endeavor.

As you know, FNIH only holds two Board meetings a year; given that our mission is to support NIH, your presence at these meetings is essential to our success. Thus, as you have done in the past, we would be most appreciative if you could make a presentation highlighting key initiatives, particularly those in which FNIH could be of help. In particular, we would be most interested in hearing about progress on the Target Validation initiative and on the newly announced Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative.

Thank you for your support of FNIH, we hope to see you in Chicago on May 14/15.

With warm regards,

President and Executive Director

Foundation for the NIH

**Sent:** Tue, 5 Mar 2013 11:57:07 -0500 **To:** Collins, Francis (NIH/OD) [E]

Cc: McManus, Ayanna (NIH/OD) [E];Ashby, Ann (FNIH) [T];Gray, Felicia (FNIH) [T]

Subject: FNIH May Board Dinner and Meeting

Dear Francis,

The FNIH Board dinner will take place on May 21<sup>st</sup> and the meeting will be held on May 22<sup>nd</sup>. I know that, unfortunately, you are scheduled to be out of town. In the even that you would be in town, I wanted to make sure you knew that you had a place of honor at the ready. The dinner should be interesting – I've asked our contact at NFL to say a few words and it is possible that Dr. John York, the owner of the 49ers may be able to come as well. And, of course, Kathy is most welcome; I have already called her office and will write a confirmatory note.

In the meantime, we are still on for our monthly meetings so you should be well-informed of our activities.

All the best, Maria

**Sent:** Mon, 24 Feb 2014 13:39:53 -0500 **To:** Collins, Francis (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Folkers, Richard

(NIH/NCI) [E]

Subject: Lurie Prize Announcement

Attachments: Lurie Prize 2014 press release final.pdf

EMBARGOED UNTIL 12:01am February 25, 2014

Dear Francis,

I am very pleased to let you know that tomorrow FNIH will be announcing the selection of Jennifer Doudna, HHMI Investigator and Professor at UC Berkeley, as the second winner of the Lurie Prize in the Biomedical Sciences.

As you may know, Jennifer, who is also NIH grantee (please see list below), discovered the gene-editing technique called CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats), which was one of Science Magazine's runners-up for 2013 breakthrough of the year. Sol Snyder, who chaired the 6-person committee as he did last year, said that the competition was tough (which is very good for us) but that they thought her work was absolutely stellar. Please see the attached embargoed press release.

We will bestow the Prize to Jennifer on <u>May 20<sup>th</sup></u> at the FNIH Award Ceremony at the Great Hall of the National Academies of Science in DC. This is the evening prior our Board meeting. I understand that you will be on international travel – NOOOOOO! Well, with your help (and John's) perhaps we can figure out how to have you "present" like we did in Chicago for last year's Lurie Prize with your Sequestration Blues. That song went viral!

I will send you a formal invitation letter to the FNIH Award Ceremony in case your calendar changes and you are able to join us for the Award dinner and the Board meeting on the 21<sup>st</sup> of May.

All the best, Maria

## Doudna's NIH Grants per RePORTER:

- SIG (OD/NCRR?) June 1, 2013 to May 31, 2014);
- R01 (NIGMS) since 2005. It is up for renewal this year;
- P50 (NIGMS) awarded in 2013 through the NIGMS Centers for HIV/AIDS-Related Structural Biology.



# Foundation for the NIH to Award Lurie Prize in the Biomedical Sciences to Jennifer Doudna from UC Berkeley

### Medal recognizes work studying RNA

Embargoed for release Tuesday, February 25, 2014 12:01 a.m., EST

#### Media Contacts:

Richard Folkers Foundation for the NIH (301) 435-2613 rfolkers@fnih.org Alison Hendrie
Rubenstein Communications
(212) 843-8029
ahendrie@rubenstein.com

The Foundation for the National Institutes of Health (FNIH) has selected Jennifer Doudna, Ph.D., a Professor from the University of California, Berkeley, as the second winner of its Lurie Prize in the Biomedical Sciences. Doudna, a Howard Hughes Investigator and Professor of Biochemistry, Biophysics and Structural Biology, will be presented the Lurie Prize medal and a \$100,000 honorarium on May 20 in Washington, D.C.

Doudna's work centers on RNA molecules, which carry out the instructions of DNA by encoding and controlling the expression of genetic information. Her laboratory focuses on the molecular structures of RNA molecules, in order to better understand their biologic function.

"It is an honor to receive the Lurie Prize," Doudna said, "particularly because it represents the work of a great many colleagues, collaborators and students, who are all dedicated to rigorous science and continual research progress."

Doudna, who is also a grantee of the National Institutes of Health and the National Science Foundation, was selected for the award by a jury of six distinguished biomedical researchers, working under the auspices of FNIH, and chaired by Solomon H. Snyder, M.D., Director-Emeritus of The Solomon H. Snyder Department of Neuroscience at Johns Hopkins University.

Along with colleagues at UC Berkeley and in Sweden, Doudna, in 2012, discovered a gene-editing technique called CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats). The technology "gives researchers the equivalent of a molecular surgery kit for routinely disabling, activating or changing genes," wrote Science magazine in a Dec. 2013 article naming CRISPR one of its runners-up for breakthrough of the year. CRISPR "has become red hot in the past year," the journal article said.

"CRISPR is, indeed, an exciting area of science, and it will be most fascinating to watch as additional research moves it closer to clinical applications," said Charles A. Sanders, M.D., FNIH Chairman, whose former titles include General Director of Massachusetts General Hospital, Professor of Medicine at

Harvard Medical School and CEO of Glaxo Inc. "Jennifer Doudna has not only contributed a groundbreaking technology, she has advanced her entire field."

Endowed by philanthropist and FNIH board member Ann Lurie, the annual prize recognizes outstanding achievement by a promising scientist age 52 or younger. Lurie is President of the Ann and Robert H. Lurie Foundation, which she began with her late husband; President of Lurie Holdings; and Founder of Africa Infectious Disease Village Clinics, Inc.

"Biomedical science has always been a challenging field, requiring researchers to continually search for new grants and other sources of funding. I am pleased to be able to play a part in the career development of scientists who will enhance their fields for years to come," said Lurie.

"The FNIH is deeply invested in helping develop the next generation of biomedical scientists," said Maria Freire, Ph.D., President of the FNIH. "There are pressing needs across a spectrum of diseases, and fostering the best minds and their innovative ideas must always be a priority."

The Lurie Prize was first awarded in 2013 to Ruslan M. Medzhitov, Ph.D., of Yale University.

-30-

Photographs and video of Jennifer Doudna are available on request.

### About the Foundation for the NIH

The Foundation for the National Institutes of Health creates and manages alliances with public and private institutions in support of the mission of the NIH, the world's premier medical research agency. The Foundation, also known as the FNIH, works with its partners to accelerate key issues of scientific study and strategies against diseases and health concerns in the United States and across the globe. The FNIH organizes and administers research projects; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of health issues. Established by Congress in 1996, the FNIH is a not-for-profit 501(c)(3) charitable organization. For additional information about the FNIH, please visit www.fnih.org.

**Sent:** Mon, 25 Feb 2013 13:13:59 -0500

To: Lori Franklin

(Ifranklin6514@gmail.com);blairdeeda@gmail.com;bloomgardenk@ruderfinn.com; (6) (6)

Collins, Francis (NIH/OD)

(b) (6)

;doug@sherrylansingfoundation.org;'freda.lewis-

hall@pfizer.com';'Edison.Liu@jax.org' (b) (6) ;jmarcus@are.com; (b) (6);'ka

ren.keyes@latonaassociates.com';'marty@AMedConsulting.com';'garry@appletreepartners.com'; (b) (6) ';'john.porter@hoganlovells.com'; (b) (6) ';'max.coslov@edmondjsafra.org'

;Sigal, Ellen (esigal@sigal.com);Sol Snyder

(ssnyder@jhmi.edu); (b) (6); 'sthier@partners.org'; (b) (6); 'lbrady@drexel

med.edu'; (b) (6) v'; 'pwalsh@jhmi.edu' **Subject:** Lurie Prize Winner Announcement

Attachments: LuriePrize Embargoed Press Release 2-25-13.pdf, Medzhitov background.docx

CONFIDENTIAL - INFORMATION EMBARGOED UNTIL FEBRUARY 26, 2013, 10AM EST

Dear Members of the Board,

We are pleased share with you, in confidence, the press release announcing the first Lurie Prize winner: Ruslan Medzhitov, PhD. Dr. Medzhitov is the David W. Wallace Professor of Immunobiology and Howard Hughes Medical Institute Investigator at the Yale University School of Medicine. For your information and use, we have included a very short background paper outlining Dr. Medzhitov's work.

You will recall that in 2012, Ms. Ann Lurie, a Member of this Board, graciously established the Lurie Prize at the FNIH as an award recognizing outstanding achievement by a young biomedical scientist. The prize amount is \$100,000, to be used as the awardee chooses. The Lurie Prize jury is chaired by Dr. Sol Snyder, Vice Chairman for Science on the FNIH Board. Sol recruited a diverse group of five distinguished scientists with wide-ranging expertise to serve on the prize jury. To our delight, over 150 nominations were submitted for consideration.

The Lurie Prize award ceremony, where Dr. Medzhitov will be presented with a medal, will be held on May 14, 2103, at Northwestern University. The Honorable John Porter, Vice Chairman for Policy of the FNIH Board, will open the evening proceedings and NIH Director Dr. Francis Collins will deliver the keynote address. The event will be sponsored through the fundraising efforts of the FNIH.

You will be soon receiving your "save the date" cards – we look forward to seeing you there!

With warm regards, Maria

# EMBARGOED UNTIL FEBRUARY 26, 2013, 10 AM EST



FROM: The Foundation for the National Institutes of Health

Bethesda, Maryland

CONTACT: Rubenstein Communications, Inc.

Alison Hendrie 212-843-8029 <u>ahendrie@rubenstein.com</u> Alexandra Sturm 212-843-9342 <u>asturm@rubenstein.com</u>

# FOUNDATION FOR THE NIH ANNOUNCES LURIE PRIZE RECOGNIZING OUTSTANDING ACHIEVEMENT BY A YOUNG BIOMEDICAL SCIENTIST

# Ruslan M. Medzhitov, PhD to Receive Inaugural Prize for Ground-Breaking Work Exploring the Immune System

**Bethesda, MD** (February 26, 2013) - The Foundation for the National Institutes of Health (FNIH) today announced that Ruslan M. Medzhitov, PhD, David W. Wallace Professor of Immunobiology and Howard Hughes Medical Institute Investigator at Yale University School of Medicine, has been awarded the inaugural Lurie Prize in the Biomedical Sciences for seminal discoveries related to the innate immune system, the human body's first line of defense against invading organisms which cause infection.

A jury of eminent scientists headed by Solomon Snyder, MD, Director-Emeritus of The Solomon H. Snyder Department of Neuroscience at Johns Hopkins University, selected Medzhitov, 46, for the honor from a group of 154 nominees. The annual prize honors early-career researchers whose findings have advanced basic biomedical science. The award, which carries an honorarium of \$100,000, will be presented to Medzhitov at a ceremony on Tuesday, May 14 in Chicago.

The innate immune system rapidly mobilizes a response to infection and, together with the adaptive immune system, is crucial to protecting human health. In laying out the rationale for granting the award, Snyder said Medzhitov discovered and characterized a class of proteins called Toll-like receptors which recognize and facilitate the immune response to toxic proteins.

"Dr. Medzhitov's painstaking studies paved the way for the identification of multiple TLR family members and their respective ligands which help bind molecules forming larger complexes, advancing the entire field of immunology and opening the way for the development of new vaccines and treatments," Snyder said. "He is a true pioneer of medical science."

Born in Tashkent in the former Soviet Republic of Uzbekistan, Dr. Medzhitov studied biology and biochemistry when financial resources for scientific research were scarce. While pouring over single copies of medical journals, he discovered an article by Dr. Charles A. Janeway, Jr. that sparked his interest in immunology and eventually led to a fellowship in the U.S. and current professorship in immunobiology at Yale University, in New Haven, Connecticut.

"I am very grateful to be the first recipient of the Lurie Prize and appreciate the recognition of not only my own work but that of young scientists in biomedical research who will be so recognized in the future," said Medzhitov.

The Lurie Prize was established by well-known, global philanthropist Ann Lurie. It reflects her passion for advancing biomedical research and medical care. Her significant financial commitments have launched and benefitted research and development, as well as patient care initiatives at the University of Michigan; Northwestern University; the recently-dedicated Ann & Robert H. Lurie Children's Hospital of Chicago; and health initiatives in Kenya, China and Rwanda.

"My specific interest is to reward and acknowledge a scientist who makes a discovery that is clearly a game changer in terms of medical and biological research," said Ms. Lurie.

The Lurie Prize recognizes young scientists, defined as individuals under the age of 52, who have made paradigm changing contributions to biomedical research.

"The Lurie Prize celebrates biomedical research and more importantly, the most outstanding young investigator on the basis of his or her body of work," said Maria Freire, PhD, President of the FNIH. "Dr. Medzhitov is one of the most brilliant scientists in the field of immunology today and we are proud to present to him this inaugural prize."

"The FNIH is grateful to Ann Lurie for her tireless work in promoting investment in medical research," said Charles A. Sanders, MD, Chairman of the FNIH. "We are particularly thankful for her unwavering support of young scientists like Dr. Medzhitov whose work is leading the way in the field of immunology."

For more information on Dr. Medzhitov's discovery and the Lurie Prize, please visit: www.fnih.org.

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## About the Foundation for the NIH

Established by the United States Congress to support the mission of the NIH—improving health through scientific discovery in the search for cures—the Foundation for the NIH is a leader in identifying and addressing complex scientific and health issues. The foundation is a non-profit, 501(c)(3) charitable organization that raises private-sector funds for a broad portfolio of unique programs that complement and enhance NIH priorities and activities. For additional information about the Foundation for the NIH, please visit www.fnih.org.

# Medzhitov and the discovery of the Human Toll-like Receptors

Ruslan Medzhitov was born in 1966 in Tashkent, to a family of mathematicians. He studied biology at Tashkent University and went on to study biochemistry at Moscow State University, earning a Ph.D. in 1993. He faced significant adversity during his education, including 2 years of conscripted service in the Soviet Army that interrupted his undergraduate studies.

While in graduate school, financial resources for scientific research were so scarce that he did not have the opportunity to gain laboratory experience. Instead, he spent most of his time in the library reading the single copies of modern medical journals available. This is when he first came across a paper in which the late Yale professor Dr. Charles Janeway outlined his controversial theory on how the innate immune system recognizes pathogens. This paper sparked his interest and prompted him to begin communicating with Janeway, who would become his mentor.

The **innate immune system** is our first line of defense against infection. This evolutionarily ancient system is made up of cells (such a macrophages and dendritic cells) and mechanisms that can immediately recognize pathogens and promptly respond to protect us from these invaders.

As critical as it is, the innate immune system does not confer long-lasting protection. This is the job of our adaptive or acquired immune system.

The adaptive immune system is composed of processes and highly specialized cells (T and B lymphocytes) that eliminate or prevent the growth of the pathogens. T and B lymphocytes, however, require specific instruction to become activated and differentiated into cells that can specifically attack the invading pathogen. So…

How does the innate immune system get activated once a microbe has infected us? and…

How does our adaptive immune system know how to differentiate its cells to complete the task?

In 1989, Charles Janeway had a radical explanation: he proposed that invading pathogens must somehow express invariant molecular patterns, like standard signatures, that would be recognized by receptors on our innate immune system cells. Janeway further suggested that

these first responders would then trigger a series of signals that would activate our second line of defense – the adaptive immune system.

This was at odds with the mainstream thinking at the time and Janeway's ideas were largely ignored by the scientific community – until, that is, Ruslan Medzhitov joined Janeway's lab.

Intrigued, Medzhitov set out to find these hypothetical receptors, molecules that could first detect microbial products and then activate specialized cells to induce immunity and inflammation (the reaction of vascular tissues to pathogens and other negative stimuli). He was aware of some existing information about inflammatory signaling pathways; so guided by this, he started a painstaking, systematic quest for molecules that could activate the immune response pathways.

In 1997, Medzhitov published a seminal paper on work funded by the National Institutes of Health that proved Janeway's theory. He had identified a protein that could activate both the innate and the adaptive immune responses: the human Toll-like receptor (TLR).

The discovery transformed the field and led to unprecedented interest in the processes and cells involved in immune signaling. Today, thanks to this body of work, we know a great deal about the mechanisms of microbial pattern recognition and we also know that, in addition to TLRs, there are several other families of receptors that are involved in immune response, some of which span membranes and others that are found inside the cell.

There is a growing suspicion, however, that there are additional types of innate immune sensing mechanisms that are not based on pattern recognition but rather on other principles. Ruslan Medzhitov finds this very intriguing.

We cannot wait to find out what he discovers.

 Sent:
 Sat, 30 Mar 2013 10:23:45 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Paul Herrling

Francis, here is Paul's reply to the question about his retirement. M.

From: Paul herrling [mailto: (b) (6)

Sent: Saturday, March 30, 2013 5:28 AM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: Two things

(b) (6)

From: Freire, Maria (FNIH) [T]
Sent: 29/03/2013 21:41
To: (b) (6)'
Subject: Re: Two things

Thank you, again! So, are you really retired or just pretending and working at Novartis as ever?!

**Sent:** Tue, 23 Apr 2013 13:58:02 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E];Burklow, John (NIH/OD) [E]

Subject: RE: Chicago trip plans dashed by Senate Hearing

Deal! Let us work on Colbert - we do not want to give the impression it is a favor to you...

Now, we need to think about how best communicate with Ann Lurie. John Burklow (copied here) mentioned the possibility yesterday to her staff, which I suspect is the reason Eric Nielsen called me this morning. I had no idea what he was about when he asked about your schedule. I have a call into John Porter to ask for his counsel.

Thanks, M.

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, April 23, 2013 1:48 PM

**To:** Freire, Maria (FNIH) [T] **Cc:** Hudson, Kathy (NIH/OD) [E]

Subject: RE: Chicago trip plans dashed by Senate Hearing

Hi Maria,

Be careful what you ask for! I have been thinking that it was about time for the sequestration blues to make an appearance – and this might just be the nudge that the muse needs to produce the doggerel.

Colbert? I don't think I've got that kind of pull. Do Eric and/or Ann?

Best, Francis

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, April 23, 2013 1:03 PM To: Collins, Francis (NIH/OD) [E] Cc: Hudson, Kathy (NIH/OD) [E]

Subject: RE: Chicago trip plans dashed by Senate Hearing

Ok, one parfati coming your way:

A video, yes, BUT with a song at the end (about whatever you like – why you can't be there, sequestration blues, MRSP as top priority) AND, for the cherry on top, what if we can get Stephen Colbert to introduce the song? He is a Northwestern graduate....

Let's think of what first, and then we can decide how to let Ann and Eric know. What say you? M.

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, April 23, 2013 12:07 PM

**To:** Freire, Maria (FNIH) [T] **Cc:** Hudson, Kathy (NIH/OD) [E]

Subject: Chicago trip plans dashed by Senate Hearing

Hi Maria,

I moved things around on my calendar to make it possible to travel to Chicago and attend the Lurie Prize dinner on the evening of May 14, and the FNIH Board meeting on the morning of May 15. But it seems the Senate had other plans.

The Senate Approps Subcommittee (Harkin, chair) has now announced the FY14 NIH appropriation hearing will be held on the afternoon of May 15, with me as the main witness. As you know this is a critical step in what we hope will be a rescue of the seriously damaged NIH budget. There is no way I can get to the Hearing if I am in Chicago that morning — and more than that, there are always a zillion last minute items that emerge the evening before a Hearing (as members and staff provide a heads up about what they want to ask about, and deep dives into specific details have to be made). I just can't afford to be somewhere else that evening.

So with deep regret, I am going to have to withdraw from the plans to be in Chicago in person. I will still be glad to send a video for the Lurie Prize event – and if it would help, I could also call in for some part of the FNIH Board meeting.

How would you suggest I share this news with Ann Lurie? I am sure she will be disappointed, but I hope everyone will understand this is completely out of my hands.

Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

(b) (6)

www.nih.gov/about/director

 Sent:
 Tue, 23 Apr 2013 13:03:22 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: RE: Chicago trip plans dashed by Senate Hearing

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A video, yes, BUT with a song at the end (about whatever you like – why you can't be there, sequestration blues, MRSP as top priority) AND, for the cherry on top, what if we can get Stephen Colbert to introduce the song? He is a Northwestern graduate....

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Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)

Sent: Tue, 23 Apr 2013 12:16:34 -0400 To: Collins, Francis (NIH/OD) [E] Cc: Hudson, Kathy (NIH/OD) [E]

Subject: RE: Chicago trip plans dashed by Senate Hearing

OH GEEZ! Let me pick myself from the floor and get back to you – neurons not firing from shock. Lime parfait from lemons time...

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, April 23, 2013 12:07 PM

To: Freire, Maria (FNIH) [T] Cc: Hudson, Kathy (NIH/OD) [E]

Subject: Chicago trip plans dashed by Senate Hearing

Hi Maria,

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Francis

Francis S. Collins, M.D., Ph.D. Director, National Institutes of Health (b)(6)

**Sent:** Tue, 23 Apr 2013 16:27:35 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E];Burklow, John (NIH/OD) [E]
Subject: RE: Chicago trip plans dashed by Senate Hearing

Francis,

I think a note to Ann Lure and to Eric Nielson, like the one you sent me, would be very good to do. Would that be possible? I would appreciate it if you told them you had just informed me so that they don't think I am hiding anything from them and it has the great virtue of being true. It has been quite interesting working with our friends from the north, to be honest – John may have gotten a whiff of this yesterday.

Here is their contact information:

Ann Lurie: (b) (6

Eric Nielson: egneilson@northwestern.edu

Many thanks, Maria

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, April 23, 2013 12:07 PM

**To:** Freire, Maria (FNIH) [T] **Cc:** Hudson, Kathy (NIH/OD) [E]

Subject: Chicago trip plans dashed by Senate Hearing

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Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)

**Sent:** Sun, 24 Mar 2013 22:42:39 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Lurie prize

Perhaps, she was quite stricken. I don't think she took it personally; it was more that she saw the event and the prize lose its cache and impact immediately. She has lent her name and her money for an event that will benefit the MRSP and the news was a huge disappointment. I was there to discuss details with her and Eric but she kept saying she could not focus on anything other than the news that you would not come. The meeting lasted less than 15 min.

By the way, we have invited some Members of Congress, which would have provided a good opportunity for a chat in their home territory. We'll see if they come.

Best, M.

From: Collins, Francis (NIH/OD) [E] Sent: Sunday, March 24, 2013 10:18 PM

**To**: Freire, Maria (FNIH) [T] **Subject**: Lurie prize

I'm still feeling very uneasy about this decision. Would it be helpful for me to call Ann Lurie and discuss? I wouldn't want her to think my reticence in any way reflects a lack of appreciation for her role with FNIH.

FC

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

(0) (0

**Sent:** Tue, 19 Mar 2013 16:46:05 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E];McManus, Ayanna (NIH/OD) [E];Tabak, Lawrence

(NIH/OD) [E];Hudson, Kathy (NIH/OD) [E] **Subject:** Re: Lurie Prize

Yes, that is what I meant, taking a page from your note. I should have signaled a wink on my e-mail. Not as good as you being there, but it would be great. Thanks, Francis.

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, March 19, 2013 03:06 PM

To: Freire, Maria (FNIH) [T]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E];

Hudson, Kathy (NIH/OD) [E] **Subject**: RE: Lurie Prize

Or a video?

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, March 19, 2013 2:48 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E];

Hudson, Kathy (NIH/OD) [E] **Subject:** Re: Lurie Prize

Francis, what about a taped address that we can play at the ceremony? M.

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, March 19, 2013 02:27 PM

To: Freire, Maria (FNIH) [T]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E];

Hudson, Kathy (NIH/OD) [E]

Subject: Lurie Prize

Hi Maria,

Given the awful reality of the sequester, I have been cancelling all but absolutely essential travel since March 4, and I have been asking the IC Directors to do the same. It looks now as if we will get no relief from this mindless cut of \$1.545 billion dollars for the rest of FY13, so I have decided to continue this policy – to try to preserve every available dollar for research.

So I regret that I won't be able to come to Chicago for the Lurie Prize – it would just be inconsistent to do so.

Please advise if sending a video would be helpful. I am truly sorry it has come to this.

## **Francis**

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)

**Sent:** Tue, 19 Mar 2013 14:48:02 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Tabak, Lawrence

(NIH/OD) [E];Hudson, Kathy (NIH/OD) [E] **Subject:** Re: Lurie Prize

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Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E];

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Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

(b) (6)

**Sent:** Tue, 19 Mar 2013 14:37:08 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Tabak, Lawrence

(NIH/OD) [E];Hudson, Kathy (NIH/OD) [E] **Subject:** Re: Lurie Prize

Oh, Francis, I am so sorry about this. I understand, but you can imagine it is a big blow - you were so important to the program! I suppose in the grand scheme of things, this is logical and small prize to pay. Still... All my best, always, M.

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, March 19, 2013 02:27 PM

To: Freire, Maria (FNIH) [T]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E];

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Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)

Sent:Tue, 25 Feb 2014 07:32:57 -0500To:Collins, Francis (NIH/OD) [E]Subject:Re: Lurie Prize Announcement

Thank you, Francis, that would be great!

Are you going to Fiocruz? Carlos Morel, who is a very good friend, may be worth visiting - I think he is still in charge of CDTS, the Center for Technological Development in Health. And I am sure you will go to Pharmanguinhos and Bio-Manguinhos, if you have not been there; they are a very interesting model.

Cheers, Maria

From: Collins, Francis (NIH/OD) [E]

Sent: Tuesday, February 25, 2014 07:14 AM

To: Freire, Maria (FNIH) [T]

Cc: Burklow, John (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Folkers, Richard (NIH/NCI) [E]

Subject: RE: Lurie Prize Announcement

Hi Maria,

Great choice for the Lurie Award!

And yes, I will be in Brazil that week, but we'll figure out some way for me to provide a shout out.

Best, Francis

From: Freire, Maria (FNIH) [T]

Sent: Monday, February 24, 2014 1:40 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Folkers, Richard (NIH/NCI) [E]

**Subject:** Lurie Prize Announcement

EMBARGOED UNTIL 12:01am February 25, 2014

Dear Francis,

I am very pleased to let you know that tomorrow FNIH will be announcing the selection of Jennifer Doudna, HHMI Investigator and Professor at UC Berkeley, as the second winner of the Lurie Prize in the Biomedical Sciences.

As you may know, Jennifer, who is also NIH grantee (please see list below), discovered the gene-editing technique called CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats), which was one of Science Magazine's runners-up for 2013 breakthrough of the year. Sol Snyder, who chaired the 6-person committee as he did last year, said that the competition was tough (which is very good for us) but that they thought her work was absolutely stellar. Please see the attached embargoed press release.

We will bestow the Prize to Jennifer on May 20<sup>th</sup> at the FNIH Award Ceremony at the Great Hall of the National Academies of Science in DC. This is the evening prior our Board meeting. I understand that you will be on international travel – NOOOOOO! Well, with your help (and John's) perhaps we can figure out how to have you "present" like we did in Chicago for last year's Lurie Prize with your Sequestration Blues. That song went viral!

I will send you a formal invitation letter to the FNIH Award Ceremony in case your calendar changes and you are able to join us for the Award dinner and the Board meeting on the 21<sup>st</sup> of May.

All the best, Maria

# Doudna's NIH Grants per RePORTER:

- SIG (OD/NCRR?) June 1, 2013 to May 31, 2014);
- R01 (NIGMS) since 2005. It is up for renewal this year;
- P50 (NIGMS) awarded in 2013 through the NIGMS Centers for HIV/AIDS-Related Structural Biology.

**Sent:** Mon, 25 Mar 2013 13:04:13 -0400 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** RE: Lurie prize

Francis, I should have sent Ann's contact information – sorry about that. Thanks for doing this, M.

### Ann Lurie

(b) (6)

Her assistant is Anne Beck 312.466.3804 abeck@lurieinvestments.com

From: Collins, Francis (NIH/OD) [E] Sent: Sunday, March 24, 2013 10:18 PM

To: Freire, Maria (FNIH) [T]

Subject: Lurie prize

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FC

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)

**Sent:** Wed, 24 Apr 2013 08:31:51 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Burklow, John

(NIH/OD) [E]

**Subject:** Re: Senate dashes hopes for travel to Chicago

To be clear, not that there is a song - you've told them that - but what it will be! As I said, it will be fun. M.

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, April 24, 2013 06:14 AM

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

**Subject**: Re: Senate dashes hopes for travel to Chicago

Thank you. Francis. I'm keeping the song a surprise - it will be great fun. Best, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, April 24, 2013 05:53 AM

To: lurie.ann@gmail.com < lurie.ann@gmail.com>; egneilson@northwestern.edu

<egneilson@northwestern.edu>

Cc: Freire, Maria (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: Senate dashes hopes for travel to Chicago

Dear Ann and Eric,

Following our prior conversations about the events in Chicago on May 14 – 15, I did major surgery on my calendar to attend the Lurie Prize dinner on the evening of May 14 and the FNIH Board meeting on the morning of May 15. But it seems the Senate had other plans.

The Senate Appropriations Subcommittee with jurisdiction over NIH (Harkin, chair) has now announced the FY14 NIH appropriation hearing will be held on the afternoon of May 15, with me as the main witness. As you know this is a critical step in what we hope will be a rescue of the seriously damaged NIH budget. There is no way I can get to the hearing if I am in Chicago that morning – and more than that, there are always a zillion last minute items that emerge the evening before a hearing (as Senators and their staff provide a heads up about what they may want to ask about, and deep dives into specific details have to be made). For the good of NIH, I just can't afford to be somewhere else that evening.

So with deep regret, I am going to have to withdraw from the plans to be in Chicago in person. I have just informed Maria of that unfortunate reality. I will be glad to send a video for the Lurie Prize event – and, if you like, I will even volunteer to conclude my video remarks with a song written for the occasion. If it would help, I could also call in for some part of the FNIH Board meeting.

I am very disappointed by this turn of events, as I am sure you are also -- but I hope everyone in Chicago will understand this is completely out of my hands.

With very best regards,

Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)

From: (b) (6) [T]

**Sent:** Wed, 24 Apr 2013 06:14:24 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Burklow, John

(NIH/OD) [E]

Subject: Re: Senate dashes hopes for travel to Chicago

Thank you. Francis. I'm keeping the song a surprise - it will be great fun. Best, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, April 24, 2013 05:53 AM

To: lurie.ann@gmail.com < lurie.ann@gmail.com>; egneilson@northwestern.edu

<egneilson@northwestern.edu>

Cc: Freire, Maria (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: Senate dashes hopes for travel to Chicago

Dear Ann and Eric,

Following our prior conversations about the events in Chicago on May 14 – 15, I did major surgery on my calendar to attend the Lurie Prize dinner on the evening of May 14 and the FNIH Board meeting on the morning of May 15. But it seems the Senate had other plans.

The Senate Appropriations Subcommittee with jurisdiction over NIH (Harkin, chair) has now announced the FY14 NIH appropriation hearing will be held on the afternoon of May 15, with me as the main witness. As you know this is a critical step in what we hope will be a rescue of the seriously damaged NIH budget. There is no way I can get to the hearing if I am in Chicago that morning — and more than that, there are always a zillion last minute items that emerge the evening before a hearing (as Senators and their staff provide a heads up about what they may want to ask about, and deep dives into specific details have to be made). For the good of NIH, I just can't afford to be somewhere else that evening.

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With very best regards,

Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)

**Sent:** Wed, 24 Apr 2013 14:54:32 -0400 **To:** 'ann lurie';Collins, Francis (NIH/OD) [E]

**Cc:** egneilson@northwestern.edu;Hudson, Kathy (NIH/OD) [E];Burklow, John

(NIH/OD) [E]; Porter, John E.'; Lori Franklin (b) (6) **Subject:** RE: Senate dashes hopes for travel to Chicago

Hi, Francis.

A song would be wonderful, indeed! And I completely agree with Ann – this event has been fraught with confusion since its inception. Even so, Ann's generosity is truly appreciated and we look forward to a lovely event in Chicago this year – perhaps a little dulled by the fact that you will not be there.

All the best, Maria

From: ann lurie [mailto (b) ( Sent: Wednesday, April 24, 2013 2:47 PM

To: Collins, Francis (NIH/OD) [E]

Cc: egneilson@northwestern.edu; Freire, Maria (FNIH) [T]; Hudson, Kathy (NIH/OD) [E]; Burklow, John

(NIH/OD) [E]

Subject: Re: Senate dashes hopes for travel to Chicago

# Dear Francis,

I am sorry you will not be able to attend this event, but I understand the need for you to be present at these hearings. It would be wonderful if you could send a video and the song would be an added bonus!

Perhaps I should look at this inaugural presentation of the Lurie Prize as a trial run for subsequent events and hope for the best, as it has been somewhat fraught with confusion since inception.

Thank you for your note and best wishes for a successful defense of your budget! Sincerely,

Ann

Ann Lurie 440 W. Ontario Street Chicago, IL 60654 312-466-4004

www.annlurie.com

On Wed, Apr 24, 2013 at 4:53 AM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear Ann and Eric,

Following our prior conversations about the events in Chicago on May 14 - 15, I did major surgery on my calendar to attend the Lurie Prize dinner on the evening of May 14 and the FNIH Board meeting on the morning of May 15. But it seems the Senate had other plans.

The Senate Appropriations Subcommittee with jurisdiction over NIH (Harkin, chair) has now announced the FY14 NIH appropriation hearing will be held on the afternoon of May 15, with me as the main witness. As you know this is a critical step in what we hope will be a rescue of the seriously damaged NIH budget. There is no way I can get to the hearing if I am in Chicago that morning – and more than that, there are always a zillion last minute items that emerge the evening before a hearing (as Senators and their staff provide a heads up about what they may want to ask about, and deep dives into specific details have to be made). For the good of NIH, I just can't afford to be somewhere else that evening.

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With very best regards,

Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)
www.nih.gov/about/director

From: Freire, Maria (NIH/OD) [T]

Sent: Fri, 25 Jan 2013 13:02:10 -0500

To: Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E]

Subject: BCG - target validation

Francis, I keep putting BCG off regarding a call next week, but perhaps I should just schedule it and see what they have to say. Let me know if this is NOT ok. Cheers, M.

 Sent:
 Wed, 23 Jan 2013 08:37:56 -0500

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: Fw: Following up on Target Validation Consortium

Hi Francis! I got the note below from Sarah. We are happy to meet with her, of course. It would be helpful to get a sense of where you are and what you envision before we do so to make sure we are in sync. We have a meeting on Feb 22nd, but that may be a bit far off. Please let me know how best to catch up. Best, M.

From: Cairns-Smith Sarah [mailto (b) (6)

Sent: Tuesday, January 22, 2013 11:40 PM

To: Wholley, David (FNIH) [T]; Freire, Maria (NIH/OD) [C]

Cc: Ringel Michael (b) (6) Bloom (Sartorius) Leah (b) (6)

Larson Erika (b) (6)

Subject: Following up on Target Validation Consortium

Maria, David,

I hope you are both having a great start to the New Year.

I just wanted to follow up on the Target Validation Consortium. Dr. Francis Collins indicated that he would like us to work with you on a project plan and budget for the next phase.

Would it make sense for us to set up a conference call this week and/or an in person meeting? Let us also know participation from your side for this.

I'll have my assistant, Erika Larson, follow up with assistants on your side.

Cheers,

Sarah

### Sarah Cairns-Smith

Partner and Managing Director

Assistant: Erika Larson Tel. (b) (6) (b) (6)

#### THE BOSTON CONSULTING GROUP

Exchange Place, 31st floor Boston, Massachusetts 02109 United States

Tel. (b) (6) Fax +1 617 973 1339 Mobile (b) (6)

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**Sent:** Wed, 4 Feb 2015 07:57:31 -0500

**To:** Burklow, John (NIH/OD) [E];Collins, Francis (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E];Wholley, David (FNIH) [T];Devaney, Stephanie (NIH/OD) [E];Myles, Renate (NIH/OD) [E]

Subject: Re: AMP rollout--one year ago today!

Amazing! Part of me feels it has been there for ages, another part just wonders where time went. As Kathy (aka Ms. Magpie), said yesterday, new shiny programs keep coming!

From: Burklow, John (NIH/OD) [E]

Sent: Wednesday, February 4, 2015 7:40 AM

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]; Freire, Maria (FNIH) [T]; Wholley, David

(FNIH) [T]; Devaney, Stephanie (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]

Subject: AMP rollout--one year ago today!

### John Burklow

Associate Director for Communications and Public Liaison National Institutes of Health Building 1, Room 344 1 Center Drive Bethesda, MD 20892

(b) (6) (phone)

(b) (6) (phone) (b) (6)

NIH . . . Turning Discovery Into Health®

From: Freire, Maria (NIH/OD) [T]

Sent: Fri, 25 Jan 2013 13:22:02 -0500

To: Hudson, Kathy (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E]

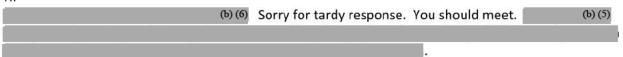
Subject: RE: BCG - target validation

Will do the call, then, no worries. M.

From: Hudson, Kathy (NIH/OD) [E] Sent: Friday, January 25, 2013 1:12 PM

To: Freire, Maria (NIH/OD) [T]
Cc: Collins, Francis (NIH/OD) [E]
Subject: Re: BCG - target validation

Hi



On Jan 25, 2013, at 12:02 PM, "Freire, Maria (NIH/OD) [T]" <mfreire@fnih.org> wrote:

Francis, I keep putting BCG off regarding a call next week, but perhaps I should just schedule it and see what they have to say. Let me know if this is NOT ok. Cheers, M.

From: Freire, Maria (NIH/OD) [E]
Sent: Thu, 6 Dec 2012 14:52:19 -0500

To: Collins, Francis (NIH/OD) [E]; (b) (6)

Cc: (b) (6) '; Hudson, Kathy (NIH/OD) [E]

Subject: Re: FNIH discussion on Target Validation Consortium

Thanks, Francis. We are looking forward to meeting you, Sarah. Best, Maria

From: Collins, Francis (NIH/OD) [E]

Sent: Thursday, December 06, 2012 02:48 PM

To: Cairns-Smith Sarah (b) (6)

Cc: Ringel Michael (b) (6) Serazin Emily (b) (6) Freire, Maria

(NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: RE: FNIH discussion on Target Validation Consortium

Totally comfortable, and it would be much appreciated!

Francis

From: Cairns-Smith Sarah [mailto (b) (6)

Sent: Thursday, December 06, 2012 11:15 AM

**To:** Collins, Francis (NIH/OD) [E] **Cc:** Ringel Michael; Serazin Emily

Subject: FNIH discussion on Target Validation Consortium

Francis,

I bumped into Stephanie James from FNIH at the ASTMH meeting a couple of weeks back. She was aware we were helping with the consortium and so suggested that it might be helpful for me to meet with Dr. Maria Freire and a couple of FNIH colleagues to give them more background on our work to date. This seemed to make sense and so I am planning to meet with them next week. I assumed this would be helpful, but wanted to check that you were comfortable with this.

Cheers,

Sarah

Sarah Cairns-Smith

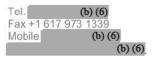
Partner and Managing Director

Assistant: Erika Larson Tel. (b) (6)

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United States



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**Sent:** Sun, 24 Mar 2013 19:59:33 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Herrling

Hi, Francis. Paul 60 60 from Novartis last year, actually. He may be still involved with the global health unit in Singapore as a member of their Board.

I am not surprised at all that Mark does not want to play. Going it alone is his trademark. By the way, my understanding is that there is not a lot of love lost between Paul and Mark. Let me dig a bit more and get back to you. M.

From: Collins, Francis (NIH/OD) [E] Sent: Sunday, March 24, 2013 07:52 PM

To: Freire, Maria (FNIH) [T]

Subject: Herrling

Hi Maria,

(b) (4)

FC

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
(b) (6)

 Sent:
 Sun, 31 Mar 2013 19:13:33 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Re: Paul Herrling

Happy Easter, Francis! I would think so; let sound him out gently. M.

From: Collins, Francis (NIH/OD) [E] Sent: Sunday, March 31, 2013 06:52 PM

**To**: Freire, Maria (FNIH) [T] **Subject**: RE: Paul Herrling

Thanks, Maria. I think in this situation of partial retirement from Novartis, we can probably justify inviting Paul to join the Target Validation Extended Steering Committee. Do you think he would be willing?

FC

From: Freire, Maria (FNIH) [T]

Sent: Saturday, March 30, 2013 10:24 AM

To: Collins, Francis (NIH/OD) [E]

Subject: Paul Herrling

Francis, here is Paul's reply to the question about his retirement. M.

From: Paul herrling [mailto (b) (6)

Sent: Saturday, March 30, 2013 5:28 AM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: Two things

(b) (6)

From: Freire, Maria (FNIH) [T]
Sent: 29/03/2013 21:41
To: (b) (6)'
Subject: Re: Two things

Thank you, again! So, are you really retired or just pretending and working at Novartis as ever?!

**Sent:** Sun, 31 Mar 2013 19:48:58 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: Paul Herrling

I am happy to do it but he would be delighted to hear from you directly, I am sure! And, naturally, you could explain it directly, circumventing the middle-man.

From: Collins, Francis (NIH/OD) [E] Sent: Sunday, March 31, 2013 7:47 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: Paul Herrling

Shall I do so, or do you want to place an informal inquiry first?

From: Freire, Maria (FNIH) [T]

**Sent:** Sunday, March 31, 2013 7:14 PM **To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: Paul Herrling

Happy Easter, Francis! I would think so; let sound him out gently. M.

From: Collins, Francis (NIH/OD) [E] Sent: Sunday, March 31, 2013 06:52 PM

**To**: Freire, Maria (FNIH) [T] **Subject**: RE: Paul Herrling

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From: Freire, Maria (FNIH) [T]

Sent: Saturday, March 30, 2013 10:24 AM

To: Collins, Francis (NIH/OD) [E]

Subject: Paul Herrling

Francis, here is Paul's reply to the question about his retirement. M.

From: Paul herrling [mailto: (b) (6)

Sent: Saturday, March 30, 2013 5:28 AM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: Two things

(b) (6)

From: Freire, Maria (FNIH) [T] Sent: 29/03/2013 21:41 To: (b) (6)

Subject: Re: Two things

Thank you, again! So, are you really retired or just pretending and working at Novartis as ever?!

Sent: Tue, 2 Apr 2013 21:51:48 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: Re: Target Validation Consortium

Woohoo! That is SO great. FYI, we've changed the date and place of the FNIH Board meeting. It is now on the morning of May 15th in Chicago. This gets about 15 Board members at the award dinner for the Lurie prize the evening before, including Paul. If you can come, it would be fantastic. However, I don't want to impose on you; time is precious, especially on the road, but I wanted you to know. Kathy suggested I invited you guys anyway, which I will do officially and gladly. Worst scenario, I brief you at our next meeting. Best, M.

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, April 02, 2013 09:20 PM

**To**: Ringel Michael (b) (6); Freire, Maria (FNIH) [T]

Subject: FW: Target Validation Consortium

From: (b) (6) [mailto (b) (6)

**Sent:** Tuesday, April 02, 2013 11:09 AM **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Target Validation Consortium

Thank you Francis,

Will try my best,

Kind regards, Paul

-----Ursprüngliche Mitteilung-----

Von: Collins, Francis (NIH/OD) [E] (NIH/OD) [E] (b) (6)

An: paulherrling (b) (6)

Cc: Ringel Michae (b) (6); Freire, Maria (FNIH) [T] <mfreire@fnih.org>;

Hudson, Kathy (NIH/OD) [E] (NIH/OD) [E] (b) (6)

Verschickt: Di, 2 Apr 2013 12:24 pm Betreff: RE: Target Validation Consortium

Hi Paul,

Despite that, we'd be glad to have your involvement, especially given FNIH's role in funding and project management.

The April 22 and June 6 dates are pretty well set – it would be great to have your participation for as much as you can manage. I am coing to Michael Ringel and Maria Freire so we can get you on board.

### Warm regards, Francis

From: (b) (6)

Sent: Tuesday, April 02, 2013 3:33 AM To: Collins, Francis (NIH/OD) [E]

Subject: Re: Target Validation Consortium

Hi Francis,

thank you for this email and I am happy to be involved

If you think my participation might still be useful then of course I am willing to contribute. The TC on 22nd April I can make the later one as during the day I am at the DNDi SAC.

June 6th I am at the end of a SAC at Dundee, it might work, but 7 June preferable.

Hope to see you at next Board meeting, I hear it might be in Chicago.

Kind regards, Paul

-----Ursprüngliche Mitteilung-----

Von: Collins, Francis (NIH/OD) [E] (NIH/OD) [E] (b) (6)

An: paulherrling (b) (6)

Cc: Freire, Maria (FNIH) [T] (FNIH) [T] <a href="mire@fnih.org">mfreire@fnih.org</a>; Ringel Michael

Verschickt: Mo, 1 Apr 2013 6:53 pm Betreff: Target Validation Consortium

Dear Paul,

I am writing to see if you would be interested and willing to participate in the Extended Steering Committee for an initiative I am co-chairing with industry leaders to improve the quality of target validation efforts between academia and industry. I think you would bring a tremendous amount of experience in helping steer the efforts, and so am hopeful you can be involved.

I know that you heard about this from me at a previous FNIH Board meeting, but a lot has been happening. The effort grew out of two joint NIH/biopharma/academia meetings that affirmed that there is strong enthusiasm for pursuing collaborative efforts to address the challenges of improving target validation. We developed the attached white paper outlining the goals for an effort, and have recently kicked off four disease area teams- Alzheimer's, Schizophrenia/related disorders, Type II diabetes, and RA/related disorders- to develop in more detail the specific research program envisioned to make progress in each area. The attached powerpoint file lists the leaders of these four teams as well as our current Steering Committee membership. The effort is being supported by FNIH and The Boston Consulting Group (BCG).

Would you be willing to participate as a member of the Extended Steering Committee? The key requests are:

- 1. Adding your name to the white paper, and (more fundamentally)
- 2. Participating by phone in two teleconferences we will have with the disease area teams to review their work and help steer their approach. These teleconferences will be an interim review on Monday, April 22nd (split into two sessions- 9.15a to 10.30a and 4.30p to 5.45p ET) and a final review on Thursday, June 6th from 1p to 4p ET.

If I can provide any more information, don't hesitate to let me know.

Kind regards,

Francis

Sent: Wed, 3 Apr 2013 21:55:58 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: Re: Target Validation Consortium

Let me know how I can help. Thanks very much, Francis.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, April 03, 2013 09:54 PM

To: Freire, Maria (FNIH) [T]

Subject: RE: Target Validation Consortium

Actually the invitation to the FNIH Board meeting may help with the justification of the trip to Chicago. Working on it....

From: Freire, Maria (FNIH) [T]

**Sent:** Tuesday, April 02, 2013 9:52 PM **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Target Validation Consortium

Woohoo! That is SO great. FYI, we've changed the date and place of the FNIH Board meeting. It is now on the morning of May 15th in Chicago. This gets about 15 Board members at the award dinner for the Lurie prize the evening before, including Paul. If you can come, it would be fantastic. However, I don't want to impose on you; time is precious, especially on the road, but I wanted you to know. Kathy suggested I invited you guys anyway, which I will do officially and gladly. Worst scenario, I brief you at our next meeting. Best, M.

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, April 02, 2013 09:20 PM

**To**: Ringel Michael (b) (6); Freire, Maria (FNIH) [T]

Subject: FW: Target Validation Consortium

From: (b) (6)

Sent: Tuesday, April 02, 2013 11:09 AM

To: Collins, Francis (NIH/OD) [E]

Subject: Re: Target Validation Consortium

Thank you Francis,

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Kind regards, Paul

| Ursprüngliche Mitteilung Von: Collins, Francis (NIH/OD) [E] (NIH/OD) [E] (b) (6) An: paulherrling (b) (6) Cc: Ringel Michael (b) (6); Freire, Maria (FNIH) [T] (FNIH) [T] < mfreire@fnih.org>; Hudson, Kathy (NIH/OD) [E] (NIH/OD) [E] < (b) (6) Verschickt: Di, 2 Apr 2013 12:24 pm Betreff: RE: Target Validation Consortium |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hi Paul,                                                                                                                                                                                                                                                                                                                       |
| (b) (4)                                                                                                                                                                                                                                                                                                                        |
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| Warm regards, Francis                                                                                                                                                                                                                                                                                                          |
| From: (b) (6) Sent: Tuesday, April 02, 2013 3:33 AM To: Collins, Francis (NIH/OD) [E] Subject: Re: Target Validation Consortium                                                                                                                                                                                                |
| Hi Francis,                                                                                                                                                                                                                                                                                                                    |
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| June 6th I am at the end of a SAC at Dundee, it might work, but 7 June preferable.                                                                                                                                                                                                                                             |
| Hope to see you at next Board meeting, I hear it might be in Chicago.                                                                                                                                                                                                                                                          |
| Kind regards, Paul                                                                                                                                                                                                                                                                                                             |
| Ursprüngliche Mitteilung Von: Collins, Francis (NIH/OD) [E] (NIH/OD) [E] (b) (6) An: paulherrling (b) (6) Cc: Freire, Maria (FNIH) [T] (FNIH) [T] < mfreire@fnih.org >; Ringel Michael (b) (6) Verschickt: Mo, 1 Apr 2013 6:53 pm Betreff: Target Validation Consortium                                                        |

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If I can provide any more information, don't hesitate to let me know.

Kind regards,

Francis

**Sent:** Tue, 22 Oct 2013 12:01:28 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: TVC

#### Right.

---- Original Message -----

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, October 22, 2013 11:54 AM

To: Freire, Maria (FNIH) [T]

Subject: RE: TVC

That's good, we want to save the big bounce for the WH.

----Original Message-----

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, October 22, 2013 11:31 AM

To: Collins, Francis (NIH/OD) [E]

Subject: TVC

Francis, Regarding my note on the announcement, the comment was very gentle and well done. Just wanted you to know that there was no preemptive move, on the contrary, an elegant teaser. M.

 Sent:
 Tue, 22 Oct 2013 11:31:18 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: TVC

Francis, Regarding my note on the announcement, the comment was very gentle and well done. Just wanted you to know that there was no preemptive move, on the contrary, an elegant teaser. M.

**Sent:** Mon, 9 Nov 2015 11:08:16 -0500 **To:** Collins, Francis (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E];Brewer, Ann (NIH/OD) [E];Burklow, John

(NIH/OD) [E]; Cather, Melissa (FNIH) [T]; Cooper, Jamie (FNIH) [T]

Subject: A feel-good true story.

Attachments: Thank you and funding grant opportunity

Dear Francis,

A few months ago, you received the attached note from the Chairman of Amie's Place Foundation (APF), a volunteer organization for "People and Pets who need each other." <a href="http://amiesplacefoundation.org/html/home.html">http://amiesplacefoundation.org/html/home.html</a>. After speaking to them, Gretchen Wood figured out they should approach FNIHI, and they did.

My staff has been working with Amie's place looking for potential projects of interest and, after some searching and matchmaking, APF has just agreed to fund (b) (4) research project (b) (4) in an upcoming RFA from NICHD entitled, "animal assisted intervention in special populations." This is wonderful, indeed!

But there is more: when Jamie Cooper, a member of my staff, spoke to Ms. Gamiel from APF late last week regarding their decision, she said that "after seeing Dr. Collins' interview with Charlie Rose, which aired on November 3, we were inspired to participate in this exciting research opportunity. His leadership is very motivating to the founder of this organization."

I thought you might like to know.

Our most sincere thanks to you, Gretchen, Ann Brewer (who was trying to be responsive to them and who we unceremoniously roped in to help), to NICHD for their help in closing this loop and to John Burklow for getting you in to see Charlie Rose! We hope this may be the first of several contributions.

All the best, as always, Maria

From: info@amiesplacefoundation.org
Sent: Mon, 11 May 2015 13:21:26 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: Thank you and funding grant opportunity

#### Dear Dr. Collins,

First of all, on behalf of the Trustees of Amie's Place Foundation, it is my privilege to thank you and your colleagues for your dedicated achievements that continue to make crucial difference for all of us. And, to be able to explore how Amie's Place Foundation may be of service.

We are all volunteers, multi-disciplinary professionals, committed to providing funding for direct service delivery programs and needed research projects that we believe can help further meet community needs. We look forward to hearing from you.

Yours truly,
Domenic J. Mizio
Chairman
Amie's Place Foundation
http://www.amiesplacefoundation.org

**Sent:** Fri, 18 Dec 2015 12:27:46 -0500

To: Collins, Francis (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]

Cc: Wholley, David (FNIH) [T]

Subject: AMP-AD

Francis, Richard – I am very pleased to tell you that we have a signed agreement with USC for AMP-AD Tau Pet Imaging grant. The money will be sent posthaste. Everyone is happy - Ho, Ho, Ho! Maria

**Sent:** Fri, 18 Mar 2016 12:35:43 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: Andrew Witty

Francis, Kathy – Below is the article on Andrew I mentioned. M.

From: BioCentury Extra [mailto:biocentury\_extra@biocentury.com]

Sent: Thursday, March 17, 2016 8:48 PM
To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: BioCentury Extra for Thursday, March 17, 2016





## March 17, 2016





Retiring Witty reveals new GSK initiatives

Chi-Med raises \$101.3M in U.S. listing

10x Genomics raises \$55M series C

Gecko closes EUR 22.5M round

Vitae surges after reporting psoriasis data

Animal data link sclerostin inhibition to joint

destruction

Kite, Genentech to study combo for NHL

FDA approves Bayer's Kovaltry

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Harness the Power of Experience and Insights

with Campbell Alliance



## Retiring Witty reveals new GSK initiatives

GlaxoSmithKline plc (LSE:GSK; NYSE:GSK) said Andrew Witty will retire as CEO on March 31, 2017. The pharma's board said it will seek a successor. Witty became CEO in 2008.

In his first speech after announcing the news, Witty previewed GSK's new commitments to global health and to novel pricing models. Speaking at the Center for Strategic and International Studies in Washington, D.C., Witty said GSK has made a "substantial commitment" to create a permanent source of vaccine research funding for potential pandemic pathogens. He said the company is close to agreements with "governments around the world" to create an R&D facility for potential pandemic threats. It would be "dedicated to developing vaccine after vaccine for likely but unpredictable Ebolas of the future."

Witty also advocated "de-linkage" of R&D costs from drug prices, especially for rare disease treatments. He said governments or other entities could pay companies for R&D costs plus a specified rate of return, and companies could then charge separately for individual "packets" of products. He added that it is "entirely possible for different parts of the system pay for each separately." Witty said GSK has publicly pegged its return target at 14%.

He suggested that GSK may attempt to test this model for autologous gene therapy <u>GSK2696273</u> to treat severe combined immunodeficiency (SCID) due to adenosine deaminase deficiency (ADA-SCID). In May, GSK submitted an MAA to EMA for the therapy (<u>see BioCentury Extra, May 5</u>). Witty challenged the pharmaceutical industry to "do something really serious in terms of access to oncology agents around the world," and said GSK hopes to make its future cancer therapies available at low cost in the poorest countries. "I am talking about the next generation of breakthrough medicines in oncology potentially going into a patent pool for the least developed countries," he said. The poorest countries would have royalty-free access to drugs donated to the patent pool, he said.

Witty also championed advance market commitments (AMCs) -- legally binding contracts to purchase specific volumes of drugs at specified prices -- to stimulate development of vaccines and drugs for diseases that primarily affect people in poor countries. Witty cited the success of an AMC in spurring development and widespread use of <a href="Synflorix">Synflorix</a> vaccine against pneumococcal disease, and said GSK is cutting the price of <a href="Synflorix">Synflorix</a> in developing countries by 10%. <a href="Back to top">Back to top</a>





# Chi-Med raises \$101.3M in U.S. listing

<u>Hutchison China MediTech Ltd.</u> (LSE:HCM; NASDAQ:HCM) lost \$0.10 to \$13.40 in its first day of trading after raising \$101.3 million through the sale of 7.5 million ADSs at \$13.50 in a NASDAQ listing. Each ADS represents half an ordinary share. BofA Merrill Lynch, Deutsche Bank Securities, Stifel, Canaccord Genuity, Panmure Gordon and CITIC are underwriters.

In October 2015, Chi-Med proposed raise up to \$100 million in the offering. Earlier this month, the company said it hoped to sell 6.1 million ADSs (see BioCentury Extra, March 7).

Chi-Med expects data next year from the Chinese Phase III FALUCA study of fruquintinib (<u>HMPL-013</u>) to treat advanced non-squamous non-small cell lung cancer (NSCLC). The company said it hopes to submit an NDA to China FDA by 1H17 for the candidate as a third-line treatment for metastatic colorectal cancer (mCRC) (see BioCentury Extra, Dec. 8, 2015).

Fruquintinib is a small molecule that selectively inhibits the tyrosine kinase activity associated with VEGF receptors.

Chi-Med slipped 420p (18%) to 1,905p in London on Thursday. Back to top

## 10x Genomics raises \$55M series C

10x Genomics Inc. (Pleasanton, Calif.) raised \$55 million in a series C round led by new investor Fidelity. New investors Softbank and JS Capital joined founding investors Venrock, Foresite Capital and Paladin Capital in the round. The company said it plans to accelerate commercialization efforts for its next-generation genome sequencing products, including GemCode and Chromium. Back to top

## Gecko closes EUR 22.5M round

<u>Gecko Biomedical S.A.S.</u> (Paris, France) raised EUR 22.5 million (\$25.1 million) in a series A2 round led by new investor <u>Sofinnova Partners</u>. <u>Bpifrance</u> also participated, as did existing investors Omnes Capital, CM-CIC Innovation and CapDecisif Management.

Gecko is developing sealants and adhesives for tissue repair based on biodegradable polymer technology. It is developing lead program GB-02 as a sealant for cardiovascular reconstruction. Sofinnova's Antoine Papiernik and <a href="mailto:Bpifrance">Bpifrance</a>'s Chahra Louafi joined Gecko's board. <a href="mailto:Back to top">Back to top</a>



# Vitae surges after reporting psoriasis data

<u>Vitae Pharmaceuticals Inc.</u> (NASDAQ:VTAE) rose \$2.68 (65%) to \$6.79 on Thursday after reporting data from 34 psoriasis patients in a Phase I/II trial of <u>VTP-43742</u>, and disclosing that it plans to start a larger, 16-week Phase II trial of the compound by YE16. <u>VTP-43742</u> is an oral small molecule inhibitor of <u>RAR</u>-related orphan receptor C thymus-specific isoform (<u>RORgamma2</u>; <u>RORgammaT</u>). In the four-week Phase IIa portion of the trial, patients receiving 350 mg of <u>VTP-43742</u> daily had a 24% reduction from baseline relative to placebo in Psoriasis Area Severity Index (PASI) score at day 28 (p=0.015), while patients receiving 700 mg had a 30% placebo-adjusted reduction (p=0.003). Vitae said the rate of reduction accelerated during the second half of the treatment period for both doses, suggesting potential for greater efficacy with longer duration of treatment.

According to the company, there were no reported serious adverse events. Reversible transaminase

elevations were observed in four patients receiving the high-dose, but the elevations did not meet the trial's stopping rules.

Vitae shares have regained some of their losses since closing at \$9.80 on March 3. Vitae tumbled 52% the next day, when the company said it stopped enrolling psoriasis patients in the trial. On a conference call on Wednesday, the company said it never began the next planned dose cohort, which would have evaluated 1,050 mg daily <a href="VTP-43742">VTP-43742</a>, due to the transaminase elevations <a href="(see BioCentury Extra, March 4)</a>. <a href="Back to top">Back to top</a>

# Animal data link sclerostin inhibition to joint destruction

A team from the University Hospital Muenster published animal <u>data</u> in *Science Translational Medicine* that show <u>sclerostin</u> inhibition promotes TNF-dependent joint destruction. In human <u>TNF alpha</u> transgenic (hTNFtg) mice, antibody-mediated inhibition of <u>sclerostin</u> led to an acceleration of rheumatoid arthritis (RA)-like disease. <u>Sclerostin</u> is a protein secreted by osteocytes that inhibits bone formation.

The researchers said <u>sclerostin</u> blocked <u>TNF alpha</u>-induced activation of p38, which they said is a key step in arthritis development. However, <u>sclerostin</u> did not block <u>interleukin-1 (IL-1)</u>-induced activation of p38, suggesting that <u>sclerostin</u> has a protective role in TNF-mediated chronic inflammation. Romosozumab (<u>AMG 785</u>), an anti-<u>sclerostin</u> mAb from <u>Amgen Inc.</u> (NASDAQ:AMGN) and <u>UCB Group</u> (Euronext:UCB), is in Phase III testing to treat osteoporosis. The partners said last month they hope to submit romosozumab to regulators this year.

In response to a question about the paper, Amgen said its researchers continually assess new findings and use them to inform development of innovative medicines.

<u>Eli Lilly and Co.</u> (NYSE:LLY) declined to comment on the study. According to Lilly's website, its antisclerostin mAb blosozumab (<u>LY2541546</u>) is in Phase I for osteoporosis. <u>Back to top</u>

# Kite, Genentech to study combo for NHL

<u>Kite Pharma Inc.</u> (NASDAQ:KITE) said it will partner with the Genentech Inc. unit of <u>Roche</u> (SIX:ROG; OTCQX:RHHBY) to conduct a clinical trial of Kite's chimeric antigen receptor (CAR) T cell therapy <u>KTE-C19</u> in combination with Genentech's anti-<u>PD-L1</u> mAb atezolizumab (<u>MPDL3280A</u>). Kite said the partners expect to begin the Phase Ib/II trial this year to treat refractory non-Hodgkin's lymphoma. Kite spokesperson Justin Jackson said the partners will co-fund the study.

Kite is conducting two Phase I/II and two Phase II trials of KTE-C19 to treat blood cancers including NHL.

Atezolizumab is under FDA review to treat urothelial carcinoma. Genentech began submitting a rolling BLA of the mAb last year to treat NSCLC (see BioCentury Extra, March 15).

<u>KTE-C19</u> consists of autologous T cells genetically modified to express a chimeric antigen receptor (CAR) targeting <u>CD19</u>. <u>Back to top</u>





## FDA approves Bayer's Kovaltry

FDA approved <u>Kovaltry</u> octocog alfa from <u>Bayer AG</u> (Xetra:BAYN) to treat hemophilia A in children and adults. Bayer said <u>Kovaltry</u> has a wholesale acquisition cost of \$1.70 per IU. In the Phase III LEOPOLD program evaluating <u>Kovaltry</u>, patients received 20-50 IU/kg of the drug twice or thrice weekly.

Last month, the European Commission approved <u>Kovaltry</u>, a plasma protein-free version of Bayer's <u>Kogenate FS</u>, a recombinant Factor VIII (rFVIII) formulated with sucrose. <u>Back to top</u>

# Priority Review for Elite's abuse-deterrent opioid

Elite Pharmaceuticals Inc. (OTCQB:ELTP) said FDA accepted and granted Priority Review to an NDA for SequestOx (ELI-200) to manage moderate to severe pain where the use of an opioid analgesic is appropriate. The PDUFA date for the abuse-deterrent formulation of oxycodone and naltrexone is July 14.

Elite gained \$0.04 (14%) to \$0.34 on Thursday. Back to top

# Express Scripts: Price, utilization drove specialty drug spending

In its annual drug trend <u>report</u>, <u>Express Scripts Holding Co.</u> (NASDAQ:ESRX) said prescription drug spending by its clients grew 5.2% in 2015, roughly half the increase reported in 2014. It said its members' average out-of-pocket spending fell 3.2% from the previous year.

The report said spending on specialty drugs increased 17.8% in 2015, driven by a 6.8% increase in utilization and an 11% increase in unit cost. Among the greatest spending increases were for cystic fibrosis drugs (53.4%) and therapies for inflammatory diseases (25%), sleep disorders (24.1%) and cancer (23.7%).

The company said it mitigated spending increases in 2015 through cost-saving initiatives for HCV drugs and reduced spending on compounded therapies. The PBM said its National Preferred Formulary, which excludes 80 medications, has generated \$3 billion in savings since 2014. Last month, CVS Health Corp. (NYSE:CVS) said its prescription drug spending increased by 5% in 2015, down from 11.8% in 2014 (see BioCentury Extra, Feb. 23). Back to top

## New dates for two FDA diabetes panels

FDA's Endocrinologic and Metabolic Drugs Advisory Committee rescheduled two meetings to discuss Type II diabetes treatments.

The committee will now meet May 24 to discuss an NDA from Novo Nordisk A/S (CSE:NVO; NYSE:NVO) for Xultophy insulin degludec/liraglutide. The therapy is a fixed dose-combination of Tresiba, a long-acting insulin analog, and Victoza, a long-acting glucagon-like peptide-1 (GLP-1) analog. The meeting was rescheduled from May 25 (see BioCentury Extra, March 16). It will now meet May 25 to discuss two NDAs from Sanofi (Euronext:SAN; NYSE:SNY). One is for glucagon-like peptide-1 receptor (GLP-1R; GLP1R) agonist lixisenatide (ZP10) alone, and the other is for a fixed-ratio combination of Lantus insulin glargine and lixisenatide. The meeting was rescheduled from May 24.

<u>Sanofi</u> markets lixisenatide in Europe as <u>Lyxumia</u>. It said last month it is still considering a proprietary name for the combo, which partner <u>Zealand Pharma A/S</u> (CSE:ZEAL) calls <u>LixiLan</u>. <u>Back to top</u>

# Legal tracks

Proskauer Rose named Fangli Chen partner and vice chair of its life science patent practice. Chen was an intellectual property partner at Choate Hall & Stewart. <u>Back to top</u>





## Senate bill would create FDA cancer institute

U.S. Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-Tenn.) and ranking member Patty Murray (D-Wash.) introduced a <u>bill</u> Thursday seeking to create one or more disease-focused "institutes" spanning FDA's centers for drugs, biologics and devices. If enacted, it is likely the first institute would be focused on cancer, mirroring a proposal from Friends of Cancer Research to create "centers of excellence" at FDA. Vice President Joe Biden has already announced that FDA will create a similar organizational structure for cancer (see BioCentury, March 7).

The FDA and NIH Workforce Authorities Modernization Act directs FDA to create one or more Intercenter Institutes to "develop and implement processes for coordination of activities" between the Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health. Each institute would aim to streamline product reviews, including for combination products, and enhance "interactions of the Centers with patients, sponsors, and the external biomedical community" in a disease area. The first would be created within about two years

after enactment.

The bill also contains provisions similar to those in the 21st Century Cures Act (<u>H.R. 6</u>) granting FDA and NIH the ability to offer higher salaries to recruit and retain staff, and reducing restrictions on travel to scientific meetings.

The HELP committee plans to debate and vote on the bill on April 6, and consider other elements of its innovation agenda the same day.

House Energy and Commerce Committee Chairman Fred Upton (R-Mich.), ranking member Frank Pallone, Jr. (D-N.J.), Rep. Diana DeGette (D-Colo.), and Sens. Alexander and Murray met Wednesday with Biden to discuss aligning H.R. 6, Senate companion legislation, and the Obama administration's National Cancer Moonshot and Precision Medicine Initiatives. Back to top

# NICE approves CDF integration

The board of the U.K.'s NICE approved changes to the agency's processes and methodology as part of its scheme to integrate the Cancer Drugs Fund (CDF) into its appraisal process. The scheme will make the CDF a "managed access" fund to pay for drugs NICE recommends conditionally.

The changes allow NICE to begin assessing cancer drugs before they are approved, require NICE to issue final guidance within 90 days of approval, and remove a 7,000-patient limitation from end-of-life criteria that allow NICE to consider a higher cost-effectiveness threshold. To qualify for the end-of-life criteria, cancer drugs would stlil need to have a cost per quality-adjusted life year (QALY) of more than L30,000 (\$43,113), treat an indication in which patients are not expected to live longer than two years, and demonstrate a survival benefit of at least three months.

The changes to NICE's processes go into effect April1, the day the existing CDF will be closed. New cancer therapies can enter the new CDF on July 1.

All current CDF drugs will continue to receive funding until NICE re-appraises them. It will begin doing so on April 1.

<u>Cancer Research UK</u> (London, U.K.) has expressed support for the proposal, but some industry groups have argued the new system will reduce patient access to cancer drugs (see BioCentury, March 14). <u>Back to top</u>





# Harness the Power of Experience and Insights with Campbell Alliance

Achieving launch excellence is a journey through learning from the successes and mistakes of the past. To achieve launch results that consistently exceed expectations, companies need to invest in

developing in-house launch excellence capabilities, supported by dedicated staff. This article details a universal launch excellence approach that can ultimately lead companies to greater efficiencies, lower costs, and far greater market success. <u>Download</u> your copy now! <u>Back to top</u>



x

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BioCentury Extra: Paul Bonanos (Editor). Meghan Sullivan, Hannah Spinrad (News Editors). Jennifer Rhodes, Steve Usdin (Washington); Becky Simon (Redwood City, Calif.); Stephen Hansen (London).

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×

Sent:Fri, 1 Jan 2016 14:10:27 -0500To:Collins, Francis (NIH/OD) [E]Subject:Automatic reply: thinking of you

Thank you for your message. I am on travel until January 12th. For urgent matters, please contact Ms. Felicia Gray at fgray@fnih.org.

**Sent:** Mon, 31 Aug 2015 11:16:56 -0400

To: Collins, Francis (NIH/OD) [E]; Hudson, Kathy (NIH/OD) [E]

Subject: (b) (6)

Francis, (b) (6)

Best, Maria

From:
Sent:
Fri, 5 Sep 2014 14:35:41 -0400
To:
Collins, Francis (NIH/OD) [E]
Subject:
Attachments:

Francis,

As promised here is

(b) (6)

Sincerely,
FC

CAFRITZ WILLIAM N. CAFRITZ William N. Cafritz died peacefully at home on August 27, 2014 from natural causes. His parents were Dr. Edward and Mildred Cafritz. He is survived by his wife, Buffy, whom he cherished, and his adopted son, Sandy Wilkes (Helen), and his daughter, Pamela Cafritz, both of whom loved their father dearly. He is also survived by his devoted brother, James Cafritz (Linda), and his three wonderful granddaughters, Elizabeth, Courtney, and Stephanie. Bill Cafritz grew up in Washington, DC where he attended Sidwell Friends School and graduated from Devitt Preparatory School where he was a gifted student and athlete. His college days were interrupted when he was drafted into the Army. As a member of the 88th Infantry Division in Italy, he was wounded in combat as his unit fought to take Monterumici. He was awarded a Purple Heart and, after convalescing, was preparing to redeploy when the war ended. After his discharge, he attended The Wharton School at The University of Pennsylvania and, soon thereafter, began a long and distinguished career as a real estate developer and investor; a career that continued until the time of his death. His projects included single family communities, garden apartments, retail centers and industrial parks. These projects were often pioneering and were frequently recognized with industry awards for their excellence and quality. His active and fulfilling life also included exemplary service to the Washington community as president of The Washington Performing Arts Society, a director of Kennedy Center Productions, Inc. and chairman of the Dacor-Bacon House building committee. He was a founding trustee of Washington Real Estate Investment Trust, a member of the executive committee of the District of Columbia Building Industry Association and vice president of the Suburban Maryland Builders Association. Always a stellar athlete with a special fondness for sailing and tennis, it was later in life that he discovered a new passion. He became a painter and sculptor. He enthusiastically took classes at The Corcoran School of Art and was awarded a muchcoveted prize for one of his sculptures. Cast in a bronze edition of three, his final sculpture captured his granddaughters sitting together happily in the company of their grandfather. With all of his accomplishments and the deep satisfaction that came from a life well-lived, it was his relationship with his wife, soul mate and companion, Buffy, that brought him his greatest joy and happiness. Theirs was a love for the ages and her endless devotion, care and encouragement during his long journey with Parkinson's Disease was nothing short of remarkable. He will always be remembered by his family and friends as a man of unmatched kindness, impeccable integrity, indomitable spirit and zest for life. Funeral and interment services are private. The family suggests that donations in his honor might be made to Caring for Military Families, 600 New Hampshire Avenue, NW Washington, DC 20037 or The William Cafritz Sculpture Fund at The National Gallery of Art, 6th and Constitution Avenue, NW, Washington, DC 20565.

**Sent:** Thu, 9 Jun 2016 11:38:53 -0400

To: Steve Paul;Lori Franklin

onovan, James (james.donovan@gs.com);Herrling, Paul (paul.herrling@novartis.com);Tom Insel;Judy Kovler (b) (6) (7);Freda.Lewis-Hall;Edison.Liu@jax.org;Ann lurie;'Joel

Marcus'; Steve Mayer; Charles, Tracey; Dr. Martin J.

Murphy;john.porter@hoganlovells.com; (b) (6);'max.coslov@edmondjsafra.org';esigal;Sol Snyder (ssnyder@jhmi.edu);'Nina Solarz';Steenberg, Russell;Stoffels, Paul [JJCUS]

(PStoffe4@its.jnj.com);sthier@partners.org;'lbrady@drexelmed.edu';Collins, Francis (NIH/OD) [E];Robert Califf

Cc: Adam, Stacey (FNIH) [T];Amoroso, Meghan (FNIH) [T];Brown, David (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Cooper, Jamie (FNIH) [T];Coyne, Eva (FNIH) [T];Donnelly, Meredith (FNIH) [T];Francis, Tiffany (FNIH) [T];Freire, Maria (FNIH) [T];Friedman, Laren (FNIH) [T];Gerlacher, Peggy (FNIH) [T];Gmicheal, Emebet (FNIH) [T];Gottlieb, Michael (FNIH) [T];Hoffmann, Steve (FNIH) [T];Hoye, Cassandra (FNIH) [T];James, Stephanie (FNIH) [T];Johns, Elizabeth (FNIH) [T];Jones-Davis, Dorothy (FNIH) [T];Klock, Kevin (FNIH) [T];Lang, Dennis (FNIH) [T];Lewis, Janelle (FNIH) [T];Mak, Jolie (FNIH) [T];Martin, Cathy (FNIH) [T];Melencio, Cheryl (FNIH) [T];Meltzer, Abbey (FNIH) [T];Menetski, Joseph (FNIH) [T];Morgan, Emily (FNIH) [T];Parrott, Dinetta (FNIH) [T];Patel, Mira (FNIH) [T];Peterson, Kathy (FNIH) [T];Powell, Susan (FNIH) [T];Sanghrajka, Anisa (FNIH) [T];Spear, Nicole (FNIH) [T];Tolentino, Will (NIH/FNIH) [T];Tountas, Karen (FNIH) [T];Tune, Julie (FNIH) [T];Whitaker, Sanya (FNIH) [T];Wholley, David (FNIH) [T];Wiener, Susan (FNIH) [T];Wolf-Rodda, Julie (FNIH) [T];Yu, Hanna (FNIH) [T];Baden, Elizabeth (NIH/OD) [E];Burklow, John (NIH/OD) [E]

**Subject:** FNIH receives PERFECT score from Charity Navigator!!!

Dear Members of the Board of Directors,

It is with great pleasure that I let you know that we have just been informed by Charity Navigator, America's largest independent charity evaluator, that once again we have received a 4-star rating (the highest they bestow) AND that we are among only 8 health charities that have obtained a perfect score = 100%. It does not get much better than that!

We are prominently featured on their site:

http://www.charitynavigator.org/index.cfm?bay=content.view&cpid=2203 and we will spread the word far and wide.

Thank you for all your help and support and many, many thanks to our outstanding team – this would not have been possible without them.

All the best, Maria

**Sent:** Tue, 9 Feb 2016 15:54:02 -0500

To: Hudson, Kathy (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Burklow, John (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]

Cc: James, Stephanie (FNIH) [T];Wolf-Rodda, Julie (FNIH) [T];Klock, Kevin (FNIH)

[T];Baden, Elizabeth (NIH/OD) [E];Higgins, Lauren (NIH/OD) [E]

Subject: Follow-up

Hi, everyone. Jeff Miller called while I was on the phone asking about next steps and follow-up. His message was that he could come down with one of his advisors to discuss plans with NIH and FNIH, which he has offered before, as you know. Has your letter to him been finalized, as was discussed in our meeting last week? It would be good to send it soon so that they know NIH's decision on next steps. If it makes sense, I can advance the notion of the symposium but I don't want to get ahead of your plans. Best, Maria

**Sent:** Fri, 5 Feb 2016 09:44:07 -0500 **To:** Collins, Francis (NIH/OD) [E]

Subject: FW: Fiocruz: Viable Zika virus particles detected in urine and saliva

Importance: High

Francis, in case you have not seen this. M.

From: Carlos Morel [mailto (b) (6)

Sent: Friday, February 05, 2016 8:56 AM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: Fiocruz: Viable Zika virus particles detected in urine and saliva

Importance: High

Dear Maria,

Informing you that now, on a live press conference, Fiocruz has reported isolation of viable zika virus particles from **saliva** and **urine** samples from clinically ill patients. Event is still going on, it can be followed on line at the following link: https://www.periscope.tv/w/1dRKZoZLWDdGB

These findings raise critical questions that needs additional research e.g. virus transmission by saliva.

Best.

Carlos

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Carlos M. Morel MD DSc

Coordenador

Instituto Nacional de C&T de Inovação em Doenças Negligenciadas (INCT-IDN)

Centro de Desenvolvimento Tecnológico em Saúde (CDTS)

Fundação Oswaldo Cruz (FIOCRUZ)

Av. Brasil 4036 - Prédio da Expansão - sala 814

CEP 21040-361 Rio de Janeiro, RJ

Tel 21-3882-9234; Fax 21-2290-0494

email morel@cdts.fiocruz.br ou

http://www.researcherid.com/citation/B-4079-2009

(b) (6)

**Sent:** Tue, 23 Feb 2016 17:14:08 -0500 **To:** Collins, Francis (NIH/OD) [E]

Subject: FW: Follow Up

Francis, FYI, M.

From: Cheryl Cole [mailto:ccole@totalwine.com] On Behalf Of David Trone

Sent: Tuesday, February 23, 2016 5:11 PM
To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: Follow Up

Thanks again for a great lunch. I really enjoyed chatting with you. I met with Francis on Saturday on his way into work and he was a wealth of great information and clearly outlined a compelling case for more research dollars. If I am successful in the campaign the NIH will certainly be priority #1.

David Trone

Phone: (301) 795-0999 Cell: (b) (6)

e-mail: dtrone@totalwine.com

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Customercare@totalwine.com of the error so that our address record can be corrected.

Sent: Sat, 21 May 2016 08:14:04 -0400

To: Collins, Francis (NIH/OD) [E]

Cc: Burklow, John (NIH/OD) [E]

Subject: FW: Please share with all staff

Importance: High

Francis, as you know, Thursday was Charlie's last day as Chairman of the FNIH Board. To mark this day (apart from the Symposium we will have in October at the NIH in his honor), we had a surprise luncheon with the Board and all the FNIH staff (red bandanas, which are Charlie's trademark, and all). He was incredibly moved and choked up a couple of times — especially when he entered the room to find everyone standing and applauding, when we handed him your letter, the staff's signed memento.... And, yes, Obama's personalized letter. I thought you might like to see his note below. M.

### To the FNIH Staff:

Yesterday has to be one of the most memorable days of my life. In the words of my grandchildren, it was just "awesome"! After all, doesn't everyone get a letter from the President when they retire from a job they love? The signed paper with all of your messages is very special and I appreciate you doing it. Plus the personal financial contributions from each of you to support the Foundation is unique and I thank you for it. Suffice to say that seeing all of you at the reception made me feel very wanted and appreciated. You were very generous and I am honored to have served as your Chairman. As I step down from the Chairmanship, I won't be saying "good-bye" but more "I will be seeing you later along the way" as we continue our journey to improve human health.

Let me commend Steve Paul to you. He will be a great Chairman. He has worked as a scientist at the NIH and he continues to be a practicing scientist. He shares our collective commitment of the mission of the Foundation and I am sure will carry it to a higher level.

Thank you again for all you have done.

Best wishes to each one of you as we go down the road to make the FNIH the best Foundation that it can possibly be.

## Charlie

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# Lori Franklin

Assistant to the Sanders Family
(b) (6)

Cell:

(b) (6)

 Sent:
 Sat, 21 May 2016 08:05:52 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Burklow, John (NIH/OD) [E]

Subject: FW: Thank you

Dear Francis,

I hope your meeting in Sweden was as great a success as your interview with Jeannie Lee at the FNIH Award Ceremony. You were absolutely terrific at making science "real" for the audience. Frankly, we have never gotten so many kudos as we did this year – thank you! Please see Jeannie's note below.

It was too bad you missed Bill Kurtis' mock "Wait, wait, don't tell me" segment. It was great fun! I have worked hard to make this ceremony different – not the usual litany of accomplishments of the awardees or self-congratulatory speeches but rather a celebration of brilliant science, done appropriately elegantly. The Q&A format has served us well, as has the absolute commitment to close the event no later than 9pm (8:45pm this year!). Thank you, again, for helping us achieve these goal and, of course, thanks to John for all his help in getting this done.

This year we had to turn people down because we simply did not have any more space- now that is a good problem to have!

All the best, as always, M.

From: Jeannie Lee [mailto:lee@molbio.mgh.harvard.edu]

Sent: Thursday, May 19, 2016 12:16 PM

**To:** Freire, Maria (FNIH) [T] <mfreire@fnih.org> **Cc:** Jeannie Lee <lee@molbio.mgh.harvard.edu>

Subject: Thank you

Dear Maria,

I have now returned to Boston but I continue to reflect on the excitement of last night's Ceremony and conversations with reporters leading up to the event. I am convinced that we as scientists need to communicate our work better and more often to the public. We need more Francis Collins! Although I was initially reluctant to take the time, I am now determined to write the Scientific American article that Josh Fischman solicited after our brief conversation on Tuesday (thanks to Jan Wootten). The public needs to know about Junk DNA and its potential for the future of medicine! It is too bad that I did not have a chance to talk about our "spare" X-chromosome and everything that can be done with it — we will save that for another time.

All this to say: MANY THANKS to the FNIH for doing what you do so well and for the incredible honor bestowed upon my lab by the Lurie Prize.

Looking forward to seeing you again in October for Charlie Sanders' Retirement Celebration.

Warmly, Jeannie

\*\*\*\*\*\*\*\*

Jeannie T. Lee, MD PhD Professor of Genetics Co-Director, Harvard Epigenetics Initiative

Howard Hughes Medical Institute
Dept. of Molecular Biology, Massachusetts General Hospital
Dept. of Genetics, Harvard Medical School
Simches 6.624
185 Cambridge St.
Boston, MA 02114

Tel: 617-726-5943

Lab Website: <a href="http://genetics.mgh.harvard.edu/LeeWeb/">http://genetics.mgh.harvard.edu/LeeWeb/</a>

Sent: Wed, 16 Dec 2015 10:47:03 -0500 To: Collins, Francis (NIH/OD) [E] Cc: Burklow, John (NIH/OD) [E]

Habemus Praemium! Subject:

## CONFIDENTIAL

Dear Francis,

I am delighted to tell you, in confidence, that the winner of the 2016 Lurie Prize is Jeannie T. Lee, M.D., Ph.D.. Jeannie is a Professor of Genetics (and Pathology), Harvard Medical School & Massachusetts General Hospital and HHMI Investigator. Do you know her? The Jury was unanimous in the selection and absolutely enthusiastic about her work. Here is an excerpt from her webpage.

Our lab studies how male (XY) and female (XX) cells use a mechanism called X-chromosome inactivation to achieve equality of sex chromosome gene expression. Our studies are focused on three noncoding RNA loci whose actions coordinate the many steps of X-chromosome inactivation. We are also interested in the mechanistic and evolutionary relationship between X inactivation and imprinting. Recent work by the Lee Lab suggests that imprinted X-chromosome inactivation is directly connected to meiotic sex chromosome inactivation in the male germline.

We are working on a press release for after the first of the year in which will recognize her NIH funding, of course. The ceremony is on May 18th, in DC.

I will let you know as soon as this is official.

Cheers, M.

**Sent:** Mon, 13 Jul 2015 09:48:16 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: Note for Ann Ashby

#### Dear Francis,

As you know, Ann Ashby will be leaving at the end of July. We are compiling a scrap book as a surprise for her with notes from people she cherished and respected while here. Would you be willing to write a note to be included in the book? I know she would love that! If it is easier, just send it electronically by next Monday so we can print it out and include it in the book.

Also, we will be having a small farewell for her at the FNIH offices the afternoon of July 30<sup>th</sup>. Your schedule is crazy, I know, but it would be lovely if you could join us. I'll send you the electronic invitation. M.

**Sent:** Wed, 23 Dec 2015 13:22:02 -0500

To: Collins, Francis (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]

Cc: Wholley, David (FNIH) [T]

Subject: RE: AMP-AD

Francis, Richard – our bank just confirmed the funds have been released to USC. They should be getting them anytime now. Best, Maria

From: Collins, Francis (NIH/OD) [E]

Sent: Sunday, December 20, 2015 8:31 AM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>; Hodes, Richard (NIH/NIA) [E] (b) (6)

Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>

Subject: RE: AMP-AD

Bravo! Making seasons bright indeed...

From: Freire, Maria (FNIH) [T]

Sent: Friday, December 18, 2015 12:28 PM

To: Collins, Francis (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]

Cc: Wholley, David (FNIH) [T]

Subject: AMP-AD

Francis, Richard – I am very pleased to tell you that we have a signed agreement with USC for AMP-AD Tau Pet Imaging grant. The money will be sent posthaste. Everyone is happy - Ho, Ho, Ho! Maria

**Sent:** Wed, 23 Dec 2015 13:49:00 -0500

To: Hodes, Richard (NIH/NIA) [E]; Collins, Francis (NIH/OD) [E]

Cc: Wholley, David (FNIH) [T];Shirdon, Patrick (NIH/NIA/ERP) [E];Barr, Robin (NIH/NIA) [E];Bernard, Marie A. (NIH/NIA) [E];Buckholtz, Neil (NIH/NIA) [E];Phelps, Creighton (NIH/NIA)

[E];Ryan, Laurie (NIH/NIA) [E];Silverberg, Nina (NIH/NIA) [E]

Subject: RE: AMP-AD

Our pleasure, Richard. Here is to a very successful 2016! Happy Holidays, everyone. M.

From: Hodes, Richard (NIH/NIA) [E]

Sent: Wednesday, December 23, 2015 1:34 PM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Wholley, David (FNIH) [T] < dwholley@fnih.org>; Shirdon, Patrick (NIH/NIA/ERP) [E]

(b) (6); Barr, Robin (NIH/NIA) [E] (b) (6); Bernard, Marie A. (NIH/NIA) (b) (6); Buckholtz, Neil (NIH/NIA) [E] (b) (6); Phelps,

Creighton (NIH/NIA) [E] (b) (6); Ryan, Laurie (NIH/NIA) [E] (b) (6)

Silverberg, Nina (NIH/NIA) [E] (b) (6)

Subject: RE: AMP-AD

Thank you Maria. This important action will facilitate efforts to maintain the A4 trial component of AMP-AD. We appreciate your efforts and those of David in overall leadership and in making this transfer of funds happen.

Best Richard

[E]

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, December 23, 2015 1:22 PM

To: Collins, Francis (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]

Cc: Wholley, David (FNIH) [T]

Subject: RE: AMP-AD

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From: Collins, Francis (NIH/OD) [E]

Sent: Sunday, December 20, 2015 8:31 AM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>; Hodes, Richard (NIH/NIA) [E] (b) (6)

Cc: Wholley, David (FNIH) [T] < dwholley@fnih.org>

Subject: RE: AMP-AD

Bravo! Making seasons bright indeed...

From: Freire, Maria (FNIH) [T]

**Sent:** Friday, December 18, 2015 12:28 PM

To: Collins, Francis (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]

**Cc:** Wholley, David (FNIH) [T] **Subject:** AMP-AD

Francis, Richard – I am very pleased to tell you that we have a signed agreement with USC for AMP-AD Tau Pet Imaging grant. The money will be sent posthaste. Everyone is happy - Ho, Ho, Ho! Maria

Sent: Sat, 7 Nov 2015 09:27:38 -0500
To: Collins, Francis (NIH/OD) [E]
Cc: dianebake@gmail.com

Subject: RE: Celebration of Safra Family Lodge

Dear Francis,

You were certainly missed at the celebration but your Ambassador, Diane, did a fabulous job – watch out, we may want to tap her over and over again!

Lilly was very moved by the testimonials and by the love and care that the NIH puts into the lodge, which was evident by how well it is kept and the number of notes and letters received.

I hope you are doing better and that the MRI sorted out what the problem is so you can get it fixed promptly!

Best, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, November 04, 2015 7:39 PM

(NIH/OD) [E] (b) (6) **Subject:** Celebration of Safra Family Lodge

Hi Maria and John,

Tomorrow's celebration of the 10<sup>th</sup> anniversary of the Safra Lodge will be a wonderfully warm and uplifting occasion. And I have been very much looking forward to it. However, as you might have heard, I am suffering rather miserably with an acute back and leg problem (probably a herniated disk, the MRI tomorrow will have something to say about that). If by some chance I am miraculously improved, I will be there with you tomorrow. Otherwise I understand that John will ably stand in for me.

The comments I plan to make, if I'm able to be there, are summarized in the attached – but John is most welcome to use part or all of this if he is called to take my place.

If I am not able to be there, it will only be because my staggering and moaning would be a distraction. Please give my very best, and my sincere gratitude, to Lily Safra, and her late husband Edmond, for what they have made possible.

Francis

**Sent:** Thu, 5 Nov 2015 07:43:37 -0500 **To:** Gallin, John (NIH/CC/OD) [E]

Cc: Collins, Francis (NIH/OD) [E];Diane Baker (b) (6);Wood,

Gretchen (NIH/OD) [E];McManus, Ayanna (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E]

Subject: Re: Celebration of Safra Family Lodge

Thanks for pitching in, John. See you in a bit. Look for Rudolf. M.

From: Gallin, John (NIH/CC/OD) [E]

Sent: Thursday, November 5, 2015 7:41 AM

To: Freire, Maria (FNIH) [T]

Cc: Collins, Francis (NIH/OD) [E]; Diane Baker (b) (6); Wood, Gretchen (NIH/OD) [E];

McManus, Ayanna (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]

Subject: Re: Celebration of Safra Family Lodge

## Francis and Maria

Sorry to hear about both of your important but hopefully just annoying problems. Francis, thanks for your comments and I will be ready whoever shows up. Rest up and get better. John

John I. Gallin, M.D. Director, Clinical Center National Institutes of Health 10 Center Drive, RM 6-2551, MSC 1504

Bethesda, MD 20892-1504

Phone: (b) (6) Fax: (301) 402-0244 Email: (b) (6)

On Nov 4, 2015, at 7:51 PM, Freire, Maria (FNIH) [T] < mfreire@fnih.org > wrote:

Oh my goodness, Francis, please take good care! I am sure you will be sorely missed (6) (6)

not sure how I will drag myself

there - what a duo! Take good care, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, November 4, 2015 7:39 PM

To: Freire, Maria (FNIH) [T]; Gallin, John (NIH/CC/OD) [E]

Cc: Diane Baker (b) (6) Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD)

[E]; Tabak, Lawrence (NIH/OD) [E]

Subject: Celebration of Safra Family Lodge

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(b) (6)

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Please give my very best, and my sincere gratitude, to Lily Safra, and her late (b) (6), for what they have made possible.

Francis

**Sent:** Wed, 4 Nov 2015 20:15:04 -0500 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: Celebration of Safra Family Lodge

Yeay, that is awesome!

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, November 4, 2015 8:10 PM

To: Freire, Maria (FNIH) [T]; Gallin, John (NIH/CC/OD) [E]

Cc: Diane Baker (b) (6); Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD)

[E]; Tabak, Lawrence (NIH/OD) [E]

Subject: RE: Celebration of Safra Family Lodge

Oh dear, please do take care yourself, Maria!

I am happy to say that Diane is utterly healthy, and will be there no matter what!

Francis

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, November 04, 2015 7:51 PM

To: Collins, Francis (NIH/OD) [E]; Gallin, John (NIH/CC/OD) [E]

Cc: Diane Baker (b) (6); Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD)

[E]; Tabak, Lawrence (NIH/OD) [E]

Subject: Re: Celebration of Safra Family Lodge

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From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, November 4, 2015 7:39 PM

To: Freire, Maria (FNIH) [T]; Gallin, John (NIH/CC/OD) [E]

Cc: Diane Baker (NIH/OD) [E]; McManus, Ayanna (NIH/OD)

[E]; Tabak, Lawrence (NIH/OD) [E]

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(b) (6

The comments I plan to make, if I'm able to be there, are summarized in the attached – but John is most welcome to use part or all of this if he is called to take my place.

Please give my very best, and my sincere gratitude, to Lily Safra, and her late (b) (6), for what they have made possible.

Francis

**Sent:** Wed, 4 Nov 2015 19:51:01 -0500

To: Collins, Francis (NIH/OD) [E]; Gallin, John (NIH/CC/OD) [E]

Cc: Diane Baker (b) (6) ;Wood, Gretchen (NIH/OD) [E];McManus,

Ayanna (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]

Subject: Re: Celebration of Safra Family Lodge

Oh my goodness, Francis, please take good care! I am sure you will be sorely missed

not sure how I will drag myself

there - what a duo! Take good care, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, November 4, 2015 7:39 PM

To: Freire, Maria (FNIH) [T]; Gallin, John (NIH/CC/OD) [E]

Cc: Diane Baker (b) (6); Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD)

[E]; Tabak, Lawrence (NIH/OD) [E]

Subject: Celebration of Safra Family Lodge

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(b)(6)

The comments I plan to make, if I'm able to be there, are summarized in the attached – but John is most welcome to use part or all of this if he is called to take my place.

(b) (6)

Please give my very best, and my sincere gratitude, to Lily Safra, and her late 60 (6), for what they have made possible.

Francis

 Sent:
 Sat, 7 Nov 2015 15:51:52 -0500

 To:
 Collins, Francis (NIH/OD) [E]

Cc: (b) (6)

Subject: RE: Celebration of Safra Family Lodge

Oh my goodness, Francis, that is no joke! Please take it easy; we all know, physicians are the worst patients and I suspect NIH directors are even worst that other physicians... Let me know if there is anything I can do – happy to help however I can. Diane, do holler, please! Best, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Saturday, November 07, 2015 9:52 AM
To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Cc: (b) (6)

Subject: RE: Celebration of Safra Family Lodge

Thanks, Maria – Diane gave me a full report on the ceremony, it sounds truly lovely. I know you were also under the weather, hope you are recovering well by now.

(b) (6)

But there are phone calls and e-mails!!!

Best, Francis

From: Freire, Maria (FNIH) [T]

Sent: Saturday, November 07, 2015 9:28 AM

To: Collins, Francis (NIH/OD) [E]

(b) (6)

Subject: RE: Celebration of Safra Family Lodge

Dear Francis,

You were certainly missed at the celebration but your Ambassador, Diane, did a fabulous job – watch out, we may want to tap her over and over again!

Lilly was very moved by the testimonials and by the love and care that the NIH puts into the lodge, which was evident by how well it is kept and the number of notes and letters received.

I hope you are doing better and that the MRI sorted out what the problem is so you can get it fixed promptly!

Best, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, November 04, 2015 7:39 PM

To: Freire, Maria (FNIH) [T] < mfreire@fnih.org >; Gallin, John (NIH/CC/OD) [E] (b) (6)

Cc: Diane Baker (b) (6) (b) (6); Wood, Gretchen (NIH/OD) [E]

(b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)

Subject: Celebration of Safra Family Lodge

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Please give my very best, and my sincere gratitude, to Lily Safra, and her late (b) (6), for what they have made possible.

Francis

**Sent:** Thu, 9 Jun 2016 12:48:52 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: FNIH receives PERFECT score from Charity Navigator!!!

Thanks for your support, Francis. Lots of hard work, lots of good people. M.

From: Collins, Francis (NIH/OD) [E] Sent: Thursday, June 09, 2016 12:43 PM To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>; Steve Paul <steve@voyagertherapeutics.com>; Lori Franklin (b) (6) (b) (6) (b) (6); Donovan, James (james.donovan@gs.com) bloomgardenk@ruderfinn.com <james.donovan@gs.com>; Herrling, Paul (paul.herrling@novartis.com) <paul.herrling@novartis.com>; Tom Insel (b) (6) Judy Kovler (b)(6)Freda.Lewis-Hall <Freda.Lewis-Hall@pfizer.com>; Edison.Liu@jax.org; Ann lurie <ann@annlurie.com>; 'Joel Marcus' <jmarcus@are.com>; Steve Mayer (b) (6):>; Charles, Tracey <tcharles@bayberryfinancial.com>; Dr. Martin J. Murphy <marty@amedconsulting.com>; john.porter@hoganlovells.com; (b) (6); 'max.coslov@edmondjsafra.org' <max.coslov@edmondjsafra.org>; esigal <esigal@sigal.com>; Sol Snyder (ssnyder@jhmi.edu) <ssnyder@jhmi.edu>; 'Nina Solarz' (b) (6); Steenberg, Russell <russ.steenberg@blackrock.com>; Stoffels, Paul [JJCUS] (PStoffe4@its.jnj.com) <PStoffe4@its.jnj.com>; sthier@partners.org; 'lbrady@drexelmed.edu' <lbrady@drexelmed.edu>; Robert Califf Cc: Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Amoroso, Meghan (FNIH) [T] <mamoroso@fnih.org>; Brown, David (FNIH) [T] <a href="mailto:cdf">dbrown@fnih.org</a>; Canet-Aviles, Rosa (FNIH) [T] <a href="mailto:cdf">rcanet-aviles@fnih.org</a>; Cooper, Jamie (FNIH) [T] < jcooper@fnih.org>; Coyne, Eva (FNIH) [T] < ecoyne@fnih.org>; Donnelly, Meredith (FNIH) [T] <mdonnelly@fnih.org>; Francis, Tiffany (FNIH) [T] <tfrancis@fnih.org>; Friedman, Laren (FNIH) [T] < | friedman@fnih.org>; Gerlacher, Peggy (FNIH) [T] < pgerlacher@fnih.org>; Gmicheal, Emebet (FNIH) [T] <egmicheal@fnih.org>; Gottlieb, Michael (FNIH) [T] <mgottlieb@fnih.org>; Hoffmann, Steve (FNIH) [T] <shoffmann@fnih.org>; Hoye, Cassandra (FNIH) [T] <choye@fnih.org>; James, Stephanie (FNIH) [T] <sjames@fnih.org>; Johns, Elizabeth (FNIH) [T] <ejohns@fnih.org>; Jones-Davis, Dorothy (FNIH) [T] <djones-davis@fnih.org>; Klock, Kevin (FNIH) [T] <kklock@fnih.org>; Lang, Dennis (FNIH) [T] <dlang@FNIH.org>; Lewis, Janelle (FNIH) [T] <jlewis@fnih.org>; Mak, Jolie (FNIH) [T] <jmak@fnih.org>; Martin, Cathy (FNIH) [T] <cmartin@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Meltzer, Abbey (FNIH) [T] <ameltzer@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>; Parrott, Dinetta (FNIH) [T] <dparrott@fnih.org>; Patel, Mira (FNIH) [T] <mpatel@fnih.org>; Peterson, Kathy (FNIH) [T] <kpeterson@fnih.org>; Powell, Susan (FNIH) [T] <spowell@fnih.org>; Sanghrajka, Anisa (FNIH) [T] <asanghrajka@fnih.org>; Spear, Nicole (FNIH) [T] <nspear@fnih.org>; Tolentino, Will (NIH/FNIH) [T] <wtolentino@fnih.org>; Tountas, Karen (FNIH) [T] <ktountas@fnih.org>; Tune, Julie (FNIH) [T] <jtune@fnih.org>; Whitaker, Sanya (FNIH) [T] <swhitaker@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Wiener, Susan (FNIH) [T] <swiener@fnih.org>; Wolf-Rodda, Julie (FNIH) [T] <jwolf-rodda@fnih.org>; Yu, Hanna (FNIH) [T] <hyu@fnih.org>; Baden, Elizabeth (NIH/OD) [E]

(b) (6) Burklow, John (NIH/OD) [E] (b) (6)

Subject: RE: FNIH receives PERFECT score from Charity Navigator!!!

Bravo!!! Well deserved!

Francis

From: Freire, Maria (FNIH) [T]

Sent: Thursday, June 09, 2016 11:39 AM

To: Steve Paul; Lori Franklin (b) (6);

bloomgardenk@ruderfinn.com; (b) (6); Donovan, James (james.donovan@gs.com); Herrling, Paul (paul.herrling@novartis.com); Tom Insel; Judy Kovler (b) (6);

Freda.Lewis-Hall; <u>Edison.Liu@jax.org</u>; Ann lurie; 'Joel Marcus'; Steve Mayer; Charles, Tracey; Dr. Martin J. Murphy; <u>john.porter@hoganlovells.com</u>; (b) (6) 'max.coslov@edmondjsafra.org'; esigal;

Sol Snyder (ssnyder@jhmi.edu); 'Nina Solarz'; Steenberg, Russell; Stoffels, Paul [JJCUS]

(<u>PStoffe4@its.jnj.com</u>); <u>sthier@partners.org</u>; 'lbrady@drexelmed.edu'; Collins, Francis (NIH/OD) [E];

Robert Califf

Cc: Adam, Stacey (FNIH) [T]; Amoroso, Meghan (FNIH) [T]; Brown, David (FNIH) [T]; Canet-Aviles, Rosa (FNIH) [T]; Cooper, Jamie (FNIH) [T]; Coyne, Eva (FNIH) [T]; Donnelly, Meredith (FNIH) [T]; Francis, Tiffany (FNIH) [T]; Freire, Maria (FNIH) [T]; Friedman, Laren (FNIH) [T]; Gerlacher, Peggy (FNIH) [T]; Gmicheal, Emebet (FNIH) [T]; Gottlieb, Michael (FNIH) [T]; Hoffmann, Steve (FNIH) [T]; Hoye, Cassandra (FNIH) [T]; James, Stephanie (FNIH) [T]; Johns, Elizabeth (FNIH) [T]; Jones-Davis, Dorothy (FNIH) [T]; Klock, Kevin (FNIH) [T]; Lang, Dennis (FNIH) [T]; Lewis, Janelle (FNIH) [T]; Mak, Jolie (FNIH) [T]; Martin, Cathy (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Morgan, Emily (FNIH) [T]; Parrott, Dinetta (FNIH) [T]; Patel, Mira (FNIH) [T]; Peterson, Kathy (FNIH) [T]; Powell, Susan (FNIH) [T]; Sanghrajka, Anisa (FNIH) [T]; Spear, Nicole (FNIH) [T]; Tolentino, Will (NIH/FNIH) [T]; Tountas, Karen (FNIH) [T]; Tune, Julie (FNIH) [T]; Whitaker, Sanya (FNIH) [T]; Wholley, David (FNIH) [T]; Wiener, Susan (FNIH) [T]; Wolf-Rodda, Julie (FNIH) [T]; Yu, Hanna (FNIH) [T]; Baden, Elizabeth (NIH/OD) [E]; Burklow, John (NIH/OD) [E]

Subject: FNIH receives PERFECT score from Charity Navigator!!!

Dear Members of the Board of Directors,

It is with great pleasure that I let you know that we have just been informed by Charity Navigator, America's largest independent charity evaluator, that once again we have received a 4-star rating (the highest they bestow) AND that we are among only 8 health charities that have obtained a perfect score = 100%. It does not get much better than that!

We are prominently featured on their site:

http://www.charitynavigator.org/index.cfm?bay=content.view&cpid=2203 and we will spread the word far and wide.

Thank you for all your help and support and many, many thanks to our outstanding team – this would not have been possible without them.

All the best, Maria

**Sent:** Tue, 9 Feb 2016 16:32:01 -0500

To: Hudson, Kathy (NIH/OD) [E];Koroshetz, Walter (NIH/NINDS) [E];Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Burklow, John (NIH/OD) [E];Wolinetz, Carrie (NIH/OD) [E]
Cc: James, Stephanie (FNIH) [T];Wolf-Rodda, Julie (FNIH) [T];Klock, Kevin (FNIH)

[T];Baden, Elizabeth (NIH/OD) [E];Higgins, Lauren (NIH/OD) [E]

Subject: RE: Follow-up

Sounds good, although I thought the NIH workshop was part of the plan that would be described in the letter. In any event, if he calls back I will simply tell him that there is a letter coming from NIH. Hang in, M.

From: Hudson, Kathy (NIH/OD) [E]

Sent: Tuesday, February 09, 2016 4:26 PM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>; Koroshetz, Walter (NIH/NINDS) [E]

(b) (6); Collins, Francis (NIH/OD) [E]

(b) (6); Tabak, Lawrence (NIH/OD) [E]

(b) (6); Wolinetz, Carrie (NIH/OD) [E]

 $\begin{tabular}{ll} \textbf{Cc: James, Stephanie (FNIH) } [T] < sjames@fnih.org>; Wolf-Rodda, Julie (FNIH) } [T] < jwolf-rodda@fnih.org>; Klock, Kevin (FNIH) } [T] < kklock@fnih.org>; Baden, Elizabeth (NIH/OD) } [E] \\ \end{tabular}$ 

(b) (6); Higgins, Lauren (NIH/OD) [E] (b) (6)

Subject: RE: Follow-up

I do not think you should raise the workshop idea with him as this will be an NIH affair and NIH will raise it with them when plans are in place and it is public information.

I will look for the letter (it may be in my pile) but there are other more pressing things today....

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, February 09, 2016 3:54 PM

To: Hudson, Kathy (NIH/OD) [E] (b) (6) >; Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) (6)

Wolinetz, Carrie (NIH/OD) [E] (b) (6)

Cc: James, Stephanie (FNIH) [T] < sjames@fnih.org>; Wolf-Rodda, Julie (FNIH) [T] < jwolf-rodda@fnih.org>; Klock, Kevin (FNIH) [T] < kklock@fnih.org>; Baden, Elizabeth (NIH/OD) [E]

(b) (6) Higgins, Lauren (NIH/OD) [E] (b) (6)

Subject: Follow-up

Hi, everyone. Jeff Miller called while I was on the phone asking about next steps and follow-up. His message was that he could come down with one of his advisors to discuss plans with NIH and FNIH, which he has offered before, as you know. Has your letter to him been finalized, as was discussed in our meeting last week? It would be good to send it soon so that they know NIH's decision on next steps. If it makes sense, I can advance the notion of the symposium but I don't want to get ahead of your plans. Best, Maria

**Sent:** Fri, 3 Jun 2016 15:17:18 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: bloomgardenk@ruderfinn.com;Burklow, John (NIH/OD) [E]

Subject: RE: Francis Collins

Hi, Francis. Sorry we could not meet again today but I understand that you have had a busy day. Below is a note from Kathy Bloomgarden, whom you know from our Board and is copied here. It sounds like a great opportunity and I know you will wow them, if you can do it. I have also copied John so he can coordinate with Kathy or her designee directly. Have a restful weekend. M.

From: Kathy Bloomgarden [mailto:bloomgardenk@RuderFinn.com]

Sent: Friday, June 03, 2016 2:30 PM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: Francis Collins

Hi Maria. I'm helping Bloomberg to put together a week of coverage on the pharma industry the week of June 29, looking at trends and big picture topics. Mike Bloomberg is going to be opening the first morning on the 29<sup>th</sup>, and they were wondering whether Francis Collins would be willing to give a keynote that morning also. I didn't know the best way to reach out to Francis, and also wanted to check if you wanted to suggest this to him. Let me know what you think is the best approach.

Hope all is well with you.

Best, Kathy

Freire, Maria (FNIH) [T] From: Sent: Sun. 20 Mar 2016 20:32:13 -0400 Glass, Roger (NIH/FIC) [E] To: Cc: Eiss, Robert (NIH/FIC) [E]; Collins, Francis (NIH/OD) [E] Subject: Re: Gates/NIH Dinner Roger, thanks for giving the go-ahead. You will get lots of credit - promise! You will recall that FNIH paid for the buffet dinner the first year we had the Gates folks on campus. We tapped a small fund that was to be used for global health activities. for dinner it was at the Cloisters and we had 55 people. My staff did all the logistics pro bono and we did not ask anyone to pay. Last year, we were out of luck. I was told about the meeting with very short notice and everyone ended at the restaurant, each paying for their meal - a bit of a nightmare, you will recall. When Rob called a few days ago, my heart sank. Again, no time to fundraise - really, guys! To avoid a repeat of last year, we looked everywhere and my staff found this small amount leftover from 15 years ago! To be absolutely clear this is not "missing" money; your folks did nothing wrong. These are leftover funds after all costs for the brochure were paid. This is a miracle! Anyway, the (b) (4) will give us enough money to have about 50 people at the Cloisters (a restaurant would severely reduce the number that could come). Nothing fancy - a buffet dinner and some wine. Again, I will ask my folks to help with the catering and logistics (with Rob's support). One alternative is to have dinner at someone's home. We could use to funds to pay for food and drinks. Any volunteers?! Roger, Francis and Rob - does the Cloisters plan make sense? Please let me know ASAP; time is running short to find the caterer. Cheers, M.

On Mar 20, 2016, at 6:45 PM, Glass, Roger (NIH/FIC) [E] (b) (6) wrote:

Hello Maria and Rob,

Congratulations for finding this missing money from (b) (5)--much before I arrived! Says something about our abilities bookkeeping at Fogarty! This is really a windfall! (Any more where this came from?)

For the dinner, do you any idea of the number of people who will be there, and what the dinner will cost. And would you anticipate that the NIHers would pay for themselves? Seems a little odd for the

smallest guys on the block to be providing Idinner for folks from the richest Foundation in the world. ... but as Maria says, this might give us some positive visibility.

If this would help Francis, I am happy to go ahead but please see what we could do to limit the damage. We do need to raise a little support for these sorts of activities in the future ...so lets put this on our agenda for next year.

Maria, appreciate your sleuthing and taking this on. You are a gem with a heart! Roger

From: Freire, Maria (FNIH) [T]

**Sent:** Friday, March 18, 2016 2:03 PM

To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]
Subject: Gates/NIH Dinner

Hi, Roger! As you know, Rob asked me if we could help support the dinner on the evening prior to the joint NIH/Gates meeting. I went back to scour every possible nook and cranny and, lo and behold, I found

(b) (4) This is a perfect use for these funds.

Francis asked me this morning about funding the dinner and I told him that, while I would not be able to come up with any funds at such short notice, we were far ahead of him and that we had these funds available and he was absolutely delighted.

Rob tells me that you are a bit reluctant to use them for this purpose. I can see your point (although neither you nor I knew we had them!) but, frankly, I can't think of a better use for them given the visibility it would give FIC and win good favor.

Please let me know your decision as soon as possible so I can confirm to Francis that this is a go – or not. Cheers, M.

Sent: Sun, 17 Apr 2016 10:47:05 -0400

Collins, Francis (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E] To: Subject: RE: Guest list for BMGF-NIH reception and dinner

See you soon, Francis.

(b) (6) M.

----Original Message----

From: Collins, Francis (NIH/OD) [E] Sent: Sunday, April 17, 2016 10:44 AM

To: Eiss, Robert (NIH/FIC) [E] Cc: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: RE: Guest list for BMGF-NIH reception and dinner

Thanks, Rob.

----Original Message----

From: Eiss, Robert (NIH/FIC) [E] Sent: Sunday, April 17, 2016 9:43 AM To: Collins, Francis (NIH/OD) [E] Cc: Freire, Maria (FNIH) [T]

Subject: Guest list for BMGF-NIH reception and dinner

Hi Francis

Below are the confirmations for this evening's event. There may be some invitees who have not responded but plan to join. Dr. Fauci sent his regrets due to a personal commitment.

There are 34 anticipated guests: 17 from NIH (plus State and FDA) and 17 from BMGF

BMGF-NIH Dinner, Hosted by FNIH

RSVPs - Updated

**BMGF** 

Niranjan Bose

Peter Dull

Emilio Emini

Sindura Ganapathi

Dan Hartman

Shasha Jumbe

Gilla Kaplan

Chris Karp

Steve Kern

Scott Miller

Trevor Mundel

Jeff Murray

Janna Patterson

Fil Randazzo

Lynda Stuart

Kirsten Vogelsong

Richard Wilder

HHS

## Luciana Borio

FNIH Maria Freire Stephanie James

Department of State Deborah Birx

NIH
Francis Collins
Kathy Hudson
Roger Glass
Peter Kilmarx
Joshua Rosenthal
Cristina Cassetti
Carl Dieffenbach
Lee Hall
Daniel Johnston
Vesna Kutlesic
Tonse Raju
Catherine Spong
George Santangelo

Sent:Wed, 16 Dec 2015 11:52:36 -0500To:Collins, Francis (NIH/OD) [E]Cc:Burklow, John (NIH/OD) [E]Subject:RE: Habemus Praemium!

Ooops, the Award date is May  $17^{th}$ , not  $18^{th}$ . The FNIH Board meeting is on the  $18^{th}$ . Sorry about that! M.

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, December 16, 2015 10:47 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Burklow, John (NIH/OD) [E] (b) (6)

Subject: Habemus Praemium!

## CONFIDENTIAL

Dear Francis,

I am delighted to tell you, in confidence, that the winner of the 2016 Lurie Prize is Jeannie T. Lee, M.D., Ph.D.. Jeannie is a Professor of Genetics (and Pathology), Harvard Medical School & Massachusetts General Hospital and HHMI Investigator. Do you know her? The Jury was unanimous in the selection and absolutely enthusiastic about her work. Here is an excerpt from her webpage.

Our lab studies how male (XY) and female (XX) cells use a mechanism called X-chromosome inactivation to achieve equality of sex chromosome gene expression. Our studies are focused on three noncoding RNA loci whose actions coordinate the many steps of X-chromosome inactivation. We are also interested in the mechanistic and evolutionary relationship between X inactivation and imprinting. Recent work by the Lee Lab suggests that imprinted X-chromosome inactivation is directly connected to meiotic sex chromosome inactivation in the male germline.

We are working on a press release for after the first of the year in which will recognize her NIH funding, of course. The ceremony is on May 18<sup>th</sup>, in DC.

I will let you know as soon as this is official.

Cheers, M.

Sent:Wed, 16 Dec 2015 11:56:15 -0500To:Collins, Francis (NIH/OD) [E]Cc:Burklow, John (NIH/OD) [E]Subject:RE: Habemus Praemium!

Please disregard the previous e-mail. I was right the first time. May 18<sup>th</sup> for 2016. I was looking at the 2017 calendar. I will go away and patch up my pride now....

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, December 16, 2015 11:53 AM

To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Cc: Burklow, John (NIH/OD) [E] <BurklowJ@OD.NIH.GOV>

Subject: RE: Habemus Praemium!

Ooops, the Award date is May  $17^{th}$ , not  $18^{th}$ . The FNIH Board meeting is on the  $18^{th}$ . Sorry about that! M.

From: Freire, Maria (FNIH) [T]

Sent: Wednesday, December 16, 2015 10:47 AM

 To: Collins, Francis (NIH/OD) [E]
 (b) (6)

 Cc: Burklow, John (NIH/OD) [E]
 (b) (6) >

Subject: Habemus Praemium!

#### CONFIDENTIAL

Dear Francis,

I am delighted to tell you, in confidence, that the winner of the 2016 Lurie Prize is Jeannie T. Lee, M.D., Ph.D.. Jeannie is a Professor of Genetics (and Pathology), Harvard Medical School & Massachusetts General Hospital and HHMI Investigator. Do you know her? The Jury was unanimous in the selection and absolutely enthusiastic about her work. Here is an excerpt from her webpage.

Our lab studies how male (XY) and female (XX) cells use a mechanism called X-chromosome inactivation to achieve equality of sex chromosome gene expression. Our studies are focused on three noncoding RNA loci whose actions coordinate the many steps of X-chromosome inactivation. We are also interested in the mechanistic and evolutionary relationship between X inactivation and imprinting. Recent work by the Lee Lab suggests that imprinted X-chromosome inactivation is directly connected to meiotic sex chromosome inactivation in the male germline.

We are working on a press release for after the first of the year in which will recognize her NIH funding, of course. The ceremony is on May 18<sup>th</sup>, in DC.

I will let you know as soon as this is official.

Cheers, M.

 Sent:
 Sun, 6 Dec 2015 21:07:53 -0500

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

Subject: Re: NFL and all that

Thank you, Francis. Let me know if you need any additional information. (b) (6)! M.

From: Collins, Francis (NIH/OD) [E]

Sent: Sunday, December 6, 2015 12:52 PM

To: Freire, Maria (FNIH) [T]
Cc: Hudson, Kathy (NIH/OD) [E]
Subject: NFL and all that

Hi Maria,

I have been cogitating about the discussion we had on Friday.

But I need to review this with the NIH Exec Comm, and we won't be able to meet this coming week

(b) (6) So hold tight for now, but that's likely to be the direction I want to go.

Thanks, Francis

**Sent:** Sun, 6 Sep 2015 06:26:53 -0400

To: Collins, Francis (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E]

Subject: Re: NIAAA project on health effects of moderate EtOH

Thank you very much, Francis! Unless I hear otherwise from either of you, we will proceed. All the best, M.

From: Collins, Francis (NIH/OD) [E]

Sent: Sunday, September 6, 2015 6:08 AM

**To:** Freire, Maria (FNIH) [T]; Hudson, Kathy (NIH/OD) [E] **Subject:** NIAAA project on health effects of moderate EtOH

Hi Maria and Kathy,

In follow up to our recent meeting, I tracked down George Koob (in New Zealand) to let him know there were some potential concerns about the upcoming project to study possible health benefits of moderate alcohol intake, funded through FNIH by donations from the beverage industry. George assured me that he would allow no interference from the funders. I expressed some concern that the PI of the planning grant had expressed sentiments suggesting he already knew what the outcome would be. NIH and FNIH need to be sure that the PI(s) chosen for this important study will design and implement a research plan that is completely objective. George clearly heard what I was saying, and assured me he would heighten his vigilance.

FC

Sent: Sat, 21 May 2016 09:05:13 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: RE: Please share with all staff

He attended the Biomarkers Consortium EC meeting yesterday by phone (Paul Herrling is an amazing Chair, by the way), so he is well on top of things.

(b) (6) but David has all our support and things are moving well on our end.

(b) (6), but with ups and downs, of course. M.

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, May 21, 2016 8:53 AM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Cc: Burklow, John (NIH/OD) [E] (b) (6)

Subject: Re: Please share with all staff

Wonderful message, wonderful tribute.

Sent from my iPhone

On May 21, 2016, at 1:14 PM, Freire, Maria (FNIH) [T] < mfreire@fnih.org > wrote:

Francis, as you know, Thursday was Charlie's last day as Chairman of the FNIH Board. To mark this day (apart from the Symposium we will have in October at the NIH in his honor), we had a surprise luncheon with the Board and all the FNIH staff (red bandanas, which are Charlie's trademark, and all). He was incredibly moved and choked up a couple of times — especially when he entered the room to find everyone standing and applauding, when we handed him your letter, the staff's signed memento.... And, yes, Obama's personalized letter. I thought you might like to see his note below. M.

## To the FNIH Staff:

Yesterday has to be one of the most memorable days of my life. In the words of my grandchildren, it was just "awesome"! After all, doesn't everyone get a letter from the President when they retire from a job they love? The signed paper with all of your messages is very special and I appreciate you doing it. Plus the personal financial contributions from each of you to support the Foundation is unique and I thank you for it. Suffice to say that seeing all of you at the reception made me feel very wanted and appreciated. You were very generous and I am honored to have served as your Chairman. As I step down from the Chairmanship, I won't be

saying "good-bye" but more "I will be seeing you later along the way" as we continue our journey to improve human health.

Let me commend Steve Paul to you. He will be a great Chairman. He has worked as a scientist at the NIH and he continues to be a practicing scientist. He shares our collective commitment of the mission of the Foundation and I am sure will carry it to a higher level.

Thank you again for all you have done.

Best wishes to each one of you as we go down the road to make the FNIH the best Foundation that it can possibly be.

Charlie

Lori Franklin

Assistant to the Sanders Family

(b) (6)

Cell:

(b) (6)

Sent: Sat, 21 May 2016 10:35:51 -0400

To: Collins, Francis (NIH/OD) [E]

Subject: Re: Please share with all staff

## Thank you, Francis.

From: Collins, Francis (NIH/OD) [E] Sent: Saturday, May 21, 2016 10:30 AM

To: Freire, Maria (FNIH) [T]

Subject: RE: Please share with all staff

(b) (6)

I will send him a note.

FC

From: Freire, Maria (FNIH) [T]
Sent: Saturday, May 21, 2016 9:05 AM
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Please share with all staff

Francis, on a sadder note -

(b) (6)

He attended the Biomarkers Consortium EC meeting yesterday by phone (Paul Herrling is an amazing Chair, by the way), so he is well on top of things.

(b) (6) but David has all our support and things are

moving well on our end. (b) (a) but with ups and downs, of course. M.

From: Collins, Francis (NIH/OD) [E] Sent: Saturday, May 21, 2016 8:53 AM

To: Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Cc: Burklow, John (NIH/OD) [E] (b) (6)

Subject: Re: Please share with all staff

Wonderful message, wonderful tribute.

Sent from my iPhone

On May 21, 2016, at 1:14 PM, Freire, Maria (FNIH) [T] < mfreire@fnih.org > wrote:

Francis, as you know, Thursday was Charlie's last day as Chairman of the FNIH Board. To mark this day (apart from the Symposium we will have in October at the NIH in his honor), we had a surprise luncheon with the Board and all the FNIH staff (red bandanas, which are Charlie's trademark, and all). He was incredibly moved and choked up a couple of times — especially when he entered the room to find

everyone standing and applauding, when we handed him your letter, the staff's signed memento.... And, yes, Obama's personalized letter. I thought you might like to see his note below. M.

# To the FNIH Staff;

Vesterday has to be one of the most memorable days of my life. In the words of my grandchildren, it was just "awesome"! After all, doesn't everyone get a letter from the President when they retire from a job they love? The signed paper with all of your messages is very special and I appreciate you doing it. Plus the personal financial contributions from each of you to support the Foundation is unique and I thank you for it. Suffice to say that seeing all of you at the reception made me feel very wanted and appreciated. You were very generous and I am honored to have served as your Chairman. As I step down from the Chairmanship, I won't be saying "good-bye" but more "I will be seeing you later along the way" as we continue our journey to improve human health.

Let me commend Steve Paul to you. He will be a great Chairman. He has worked as a scientist at the NIH and he continues to be a practicing scientist. He shares our collective commitment of the mission of the Foundation and I am sure will carry it to a higher level.

Thank you again for all you have done.

Best wishes to each one of you as we go down the road to make the FNIH the best Foundation that it can possibly be.

Charlie

Lori Franklin
Assistant to the Sanders Family
(b) (6)
Cell: (b) (6)

Sent: Mon, 14 Dec 2015 07:44:34 -0500

To: Collins, Francis (NIH/OD) [E]

Subject: Re: Portrait Gallery Dinner

Of course, happy to do so, Francis.

From: Collins, Francis (NIH/OD) [E]

Sent: Monday, December 14, 2015 7:42 AM

To: Freire, Maria (FNIH) [T]

Subject: FW: Portrait Gallery Dinner

Hey there Maria,

See note below. Would you be willing to speak with this individual?

Francis

From: Cheryl Cole [mailto:ccole@totalwine.com] On Behalf Of David Trone

Sent: Friday, December 11, 2015 9:57 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Portrait Gallery Dinner

We met at the Portrait Gallery dinner at the French Ambassador's home two weeks ago where I had the pleasure of sitting next to your wife and the issue of fundraising for medical research came up. I am the President and Co-Owner with my brother of Total Wine & More which is a \$2 billion revenue company and the largest privately owned retailer of wine, beer and spirits in the United States. Through our foundation my wife and I are involved in a number of philanthropic efforts.

My interest is to set up a one hour meeting or lunch with you to talk about NIH and medical research in the United States in general. I strongly support long term investment spending for research and have significant political relationships that could be of assistance to NIH.

My office is right down the street and I would be happy to meet you whenever you have a free hour. I am fine evenings and weekends if that would work better for you.

David Trone

Phone: (301) 795-0999 Cell: (b) (6)

e-mail: dtrone@totalwine.com

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the sender of the error by replying via email or by emailing Total Wine & More at <a href="mailto:Customercare@totalwine.com">Customercare@totalwine.com</a> of the error so that our address record can be corrected.

**Sent:** Tue, 9 Feb 2016 16:17:18 -0500 **To:** Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E];Burklow, John (NIH/OD) [E];Wolinetz, Carrie

(NIH/OD) [E]

Subject: RE: Portrait Gallery Dinner

Hi, Francis. I had a very nice lunch with David Trone, following on your suggestion below. I now understand that he must have been baffled by your reply: he is not really interested in funding FNIH (although, of course, I told him he should) but rather wanted an NIH 101 and I immediately knew why – he is running for Van Hollen's seat in Congress and one of his platforms is doubling the NIH budget. At the time you met him, he had not decided to do so but he officially declared his candidacy a few weeks back.

He is not knowledgeable about NIH, although he considers it to be of paramount importance, not only for the district but for the country and the world. He wants to take a long-term approach. No argument there. I gave him a fairly good overview, going back to basics: the 27 ICs, the CC, intramural vs. extramural, the terrible budget crunch, and even how drugs are developed.

He has asked for data, particularly the funding curve (how it has changed over time), the number of grant applications vs. the number of grants funded, etc. I am happy to provide that information (I am sure your folks have it at their fingertips — or on the website); I told him I would do so. However, it might be worth your while to have a one-on-one meeting with him to bring him up to speed; regardless of whether he wins or loses, he really needs to be educated. Let me know if I can help in any way.

Best, Maria

From: Collins, Francis (NIH/OD) [E]

**Sent:** Monday, December 21, 2015 5:31 AM **To:** David Trone <dtrone@totalwine.com> **Subject:** RE: Portrait Gallery Dinner

Dear David,

Apologies for the very slow response, it's been a remarkably busy time here at NIH.

Diane said how much she enjoyed chatting with you at the dinner. And I am glad to know of your philanthropic efforts. Because of various government rules (and there are lots of those), it is slightly awkward for me to have a conversation that involves fundraising – but fortunately the Congress created a non-profit, the Foundation for NIH (<a href="www.fnih.org">www.fnih.org</a>), for just that purpose. The President and Executive Director of FNIH, Dr. Maria Freire, is a terrific leader and is highly knowledgeable about NIH's many endeavors. I've touched base with her, and she would be glad to meet with you (mfreire@fnih.org).

Many thanks for your interest in NIH, and for your many other good works.

Francis

From: Cheryl Cole [mailto:ccole@totalwine.com] On Behalf Of David Trone

Sent: Friday, December 11, 2015 9:57 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Portrait Gallery Dinner

We met at the Portrait Gallery dinner at the French Ambassador's home two weeks ago where I had the pleasure of sitting next to your wife and the issue of fundraising for medical research came up. I am the President and Co-Owner with my brother of Total Wine & More which is a \$2 billion revenue company and the largest privately owned retailer of wine, beer and spirits in the United States. Through our foundation my wife and I are involved in a number of philanthropic efforts.

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Customercare@totalwine.com of the error so that our address record can be corrected.

**Sent:** Tue, 9 Feb 2016 21:10:46 -0500 **To:** Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E];Burklow, John (NIH/OD) [E];Wolinetz, Carrie

(NIH/OD) [E]

Subject: Re: Portrait Gallery Dinner

No problem at all; I enjoyed meeting him. M.

On Feb 9, 2016, at 9:09 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Hi Maria,

Many thanks for meeting with him. And apologies for misunderstanding his request! I'll follow up.

Best, Francis

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, February 09, 2016 4:17 PM

To: Collins, Francis (NIH/OD) [E]

Cc: Hudson, Kathy (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]

Subject: RE: Portrait Gallery Dinner

Hi, Francis. I had a very nice lunch with David Trone, following on your suggestion below. I now understand that he must have been baffled by your reply: he is not really interested in funding FNIH (although, of course, I told him he should) but rather wanted an NIH 101 and I immediately knew why — he is running for Van Hollen's seat in Congress and one of his platforms is doubling the NIH budget. At the time you met him, he had not decided to do so but he officially declared his candidacy a few weeks back.

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Best, Maria

From: Collins, Francis (NIH/OD) [E]

Sent: Monday, December 21, 2015 5:31 AM

To: David Trone < <a href="mailto:dtrone@totalwine.com">dtrone@totalwine.com</a>>
Subject: RE: Portrait Gallery Dinner

Dear David,

Apologies for the very slow response, it's been a remarkably busy time here at NIH.

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Many thanks for your interest in NIH, and for your many other good works.

Francis

From: Cheryl Cole [mailto:ccole@totalwine.com] On Behalf Of David Trone

Sent: Friday, December 11, 2015 9:57 AM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Portrait Gallery Dinner

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**David Trone** 

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 Sent:
 Fri, 27 May 2016 11:36:51 -0400

 To:
 Collins, Francis (NIH/OD) [E]

 Cc:
 Hudson, Kathy (NIH/OD) [E]

**Subject:** Re: Sorry about postponing meeting today

Thanks, Francis.

And we also have to make sure they let us know if/when it happens and not answer the phone.

As I told Kathy, we now have policies in place that we have incorporated into the "moderate drinking study" MOU with NIAAA that I flagged for you a couple of times because of similar concerns.

Onward! M.

From: Collins, Francis (NIH/OD) [E] Sent: Friday, May 27, 2016 10:26 AM

**To:** Freire, Maria (FNIH) [T] **Cc:** Hudson, Kathy (NIH/OD) [E]

**Subject:** Sorry about postponing meeting today

Hi Maria,

Kathy is at the Stanford Big Data in Biomedicine meeting, which is why today's pow-wow had to be postponed. I wanted to let you know, however, that I spoke with all of the Institute Directors yesterday morning, and let them know that we will need to avoid any future situations where a donor reaches out directly to NIH – FNIH has to be the point of contact.

Hope you are going to get a bit of a break over this Memorial Day weekend.

Best, Francis

**Sent:** Sat, 23 Apr 2016 09:41:23 -0400 **To:** Collins, Francis (NIH/OD) [E]

Subject: RE: thank you

It was a good meeting, Francis. I have already heard feedback from some Gates folks and, of course, FDA was delighted to be included. M.

From: Collins, Francis (NIH/OD) [E]
Sent: Saturday, April 23, 2016 7:18 AM

To: Borio, Luciana (FDA/OC) (b) (6)

Cc: Robert Califf (b) (6) >; Freire, Maria (FNIH) [T] <mfreire@fnih.org>

Subject: RE: thank you

Hi Lu,

Thanks for your gracious note – it was really helpful having you and Rob involved in the discussions with BMGF. Having NIH and FDA work closely together on global health issues is a great way to make progress happen!

Best, Francis

From: Borio, Luciana (FDA/OC)
Sent: Friday, April 22, 2016 7:00 PM
To: Collins, Francis (NIH/OD) [E]

Cc: Robert Califf; Freire, Maria (FNIH) [T]

Subject: thank you

Dear Dr. Collins,

I'm writing to thank you for inviting Rob and me to attend the 3<sup>rd</sup> annual NIH and BMGF meeting. I know Rob really enjoyed the substantive presentations and discussions around Zika. As you know, FDA's mission is synergistic with the missions of the NIH and BMGF. It was most generous of you to open your doors to your FDA colleagues. We have made several connections at the meeting and we are already planning a follow-up discussion to identify some key areas for collaboration between FDA and BMGF that can help advance our common goals. I don't want to miss the opportunity to thank Maria for being such a strong supporter of FDA, and for working tirelessly to advance science and public health...in addition to being the most wonderful hostess.

Have a nice weekend,

Lu

Luciana Borio, M.D.
Acting Chief Scientist
Food and Drug Administration
White Oak Building 1, Room 3317
10903 New Hampshire Ave.

**Sent:** Tue, 12 Jan 2016 14:01:37 -0500 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: thinking of you

Yes, no problem.

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, January 12, 2016 1:58 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: thinking of you

5:30 PM would be great - would that work?

FC

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, January 12, 2016 1:53 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: thinking of you

Yes, of course. I just landed. Let me get sorted out and I will give you a call. Is there a better window of time for you? M.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, January 12, 2016 1:40 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: thinking of you

Hi Maria,

I understand that you are

(b)(6)

When you arrive here, I'd like to speak with you about the Congressional interest in the NFL issues – can you give me a call at (b) (6)? I need to talk with you before the scheduled session tomorrow with House Investigation and Oversight majority staff.

Thanks, Francis

From: Freire, Maria (FNIH) [T]

**Sent:** Friday, January 01, 2016 4:36 PM **To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: thinking of you

Oh, Francis, thank you!

From: Collins, Francis (NIH/OD) [E]

Sent: Friday, January 1, 2016 1:10 PM To: Freire, Maria (FNIH) [T] Subject: thinking of you

Hi Maria,

(b) (6)

From: Freire, Maria (FNIH) [T] Sent: Tue, 12 Jan 2016 13:52:30 -0500 Collins, Francis (NIH/OD) [E] To: Subject: Re: thinking of you Yes, of course. I just landed. Let me get sorted out and I will give you a call. Is there a better window of time for you? M. From: Collins, Francis (NIH/OD) [E] **Sent:** Tuesday, January 12, 2016 1:40 PM To: Freire, Maria (FNIH) [T] Subject: RE: thinking of you Hi Maria, I understand that you are (b)(6)When you arrive here, I'd like to speak with you about the Congressional interest in the NFL issues - can (b) (6)? I need to talk with you before the scheduled session tomorrow you give me a call at with House Investigation and Oversight majority staff. Thanks, Francis From: Freire, Maria (FNIH) [T] Sent: Friday, January 01, 2016 4:36 PM To: Collins, Francis (NIH/OD) [E] Subject: Re: thinking of you Oh, Francis, thank you!

**From:** Collins, Francis (NIH/OD) [E] **Sent:** Friday, January 1, 2016 1:10 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** thinking of you

Hi Maria,

(b) (6)

 Sent:
 Fri, 1 Jan 2016 16:35:50 -0500

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Re: thinking of you

### Oh, Francis, thank you!

From: Collins, Francis (NIH/OD) [E] Sent: Friday, January 1, 2016 1:10 PM

To: Freire, Maria (FNIH) [T]
Subject: thinking of you

Hi Maria,

(b) (6)

**Sent:** Tue, 12 Jan 2016 15:06:53 -0500 **To:** Collins, Francis (NIH/OD) [E]

Subject: Re: thinking of you

Ah, right. but Kevin, my chief of staff, can talk to them so we know what they need. One way or another, I'll sort it out and make sure we are responsive. M.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, January 12, 2016 2:58 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: thinking of you

My mistake, should have said minority staff, not majority!!

From: Collins, Francis (NIH/OD) [E] Sent: Tuesday, January 12, 2016 1:58 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: thinking of you

5:30 PM would be great - would that work?

FC

From: Freire, Maria (FNIH) [T]

Sent: Tuesday, January 12, 2016 1:53 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: thinking of you

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From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, January 12, 2016 1:40 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** RE: thinking of you

Hi Maria,

I understand that you are

(b) (6)

When you arrive here, I'd like to speak with you about the Congressional interest in the NFL issues – can you give me a call at 60.60? I need to talk with you before the scheduled session tomorrow with House Investigation and Oversight majority staff.

Thanks, Francis

Sent: Friday, January 01, 2016 4:36 PM

**To:** Collins, Francis (NIH/OD) [E] **Subject:** Re: thinking of you

Oh, Francis, thank you!

From: Collins, Francis (NIH/OD) [E] Sent: Friday, January 1, 2016 1:10 PM

**To:** Freire, Maria (FNIH) [T] **Subject:** thinking of you

Hi Maria,

(b) (б)

From: Wholley, David (FNIH) [T]

**Sent:** Thu, 10 Nov 2016 14:44:59 -0500 **To:** Tabak, Lawrence (NIH/OD) [E]

Cc: Collins, Francis (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Freire, Maria (FNIH) [T]

Subject: AMP Executive Committee Co-chair role

### Dear Larry,

Francis Collins and I just spoke, and your willingness to consider taking over leadership of the Accelerating Medicines Partnership going forward is very muc appreciated. I will be happy to sit down with you anytime if you'd like me to brief you on AMP and the workings of the EC. My assistant, Cheryl Melencio, will make sure that our November 18 and all future meetings are on your calendar. Please don't hesitate if I can help with any questions.

### Regards,

# David David Wholley Director, Research Partnerships Foundation for the National Institutes of Health 9650 Rockville Pike | Bethesda, MD 20814 | fnih.org

9650 Rockville Pike | Bethesda, MD 20814 | fnih.org Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] on behalf of Wholley, David (FNIH) [T]

**Sent:** Mon, 29 Aug 2016 16:34:38 -0400

To: Buckholtz, Neil (NIH/NIA) [C];Canet-Aviles, Rosa (FNIH) [T];Carter, Robert (NIH/NIAMS) [E];Collins, Francis (NIH/OD) [E];Cuss, Francis;Decker, Mike;Dolsten, Mikael;Gadbois, Ellen (NIH/OD) [E];Hodes, Richard (NIH/NIA) [E];Hodge, Martin;Hoffmann, Steve (FNIH) [T];Hudson, Kathy (NIH/OD) [E];Katz, Stephen I. (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Lea, Allison (NIH/OD) [C];Lifton, Richard;Lundberg, Jan;Paltoo, Dina (NIH/OD) [E];Rodgers, Griffin (NIH/NIDDK) [E];Ryan, Laurie (NIH/NIA) [E];Serrate-Sztein, Susana (NIH/NIAMS) [E];Smith, Philip (NIH/NIDDK) [E];Spear, Nicole (FNIH) [T];Stein, Peter;Sutherland, Margaret (NIH/NINDS) [E];Terry, Sharon MA;Whitaker, Sanya (FNIH) [T];Wholley, David (FNIH) [T]

Cc: Boskent, Celeste (NIH/OD) [E];Bronson, Charlette (NIH/NIA) [E];Cappello, Elizabeth;Clark, Katie;Craver, Stephanie (NIH/NIAMS) [E];Doswell, Greta (NIH/OD) [E];Edmonds, Pamela;Gwaldis, Janice;Yuliya Ilchyk;McManus, Ayanna (NIH/OD) [E];Melencio, Cheryl (FNIH) [T];Meltzer, Sherry (NIH/NIAMS) [E];Morgan, Emily (FNIH) [T];Tanya Murza;NIHDirectorMeetings;Poole, Charlene (NIH/NIDDK) [E];Protasiewicz, Ann;Schulke, Hilda (NIH/OD) [E];Sheehan, Joan (NIH/NIA) [E];Walker, Paula (NIH/NINDS) [E];Wilkerson, Anita D. (NIH/NIDDK) [E];Wood, Gretchen (NIH/OD) [E];Zander, Debra

Subject: AMP Executive Committee Progress Report - August 2016
Attachments: AMP Progress Report for EC August 26 2016 final.pdf

#### Dear AMP Executive Committee:

In lieu of our regularly scheduled AMP Executive Committee Meeting on Friday, please see as promised a brief summary of progress over the last month. I look forward to speaking with you on our next AMP EC teleconference, on September 23.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health

### **Cheryl Melencio**

Executive Assistant, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 402-4970 | Fax (301) 480-2752

Combined Federal Campaign (CFC) #29165

For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.



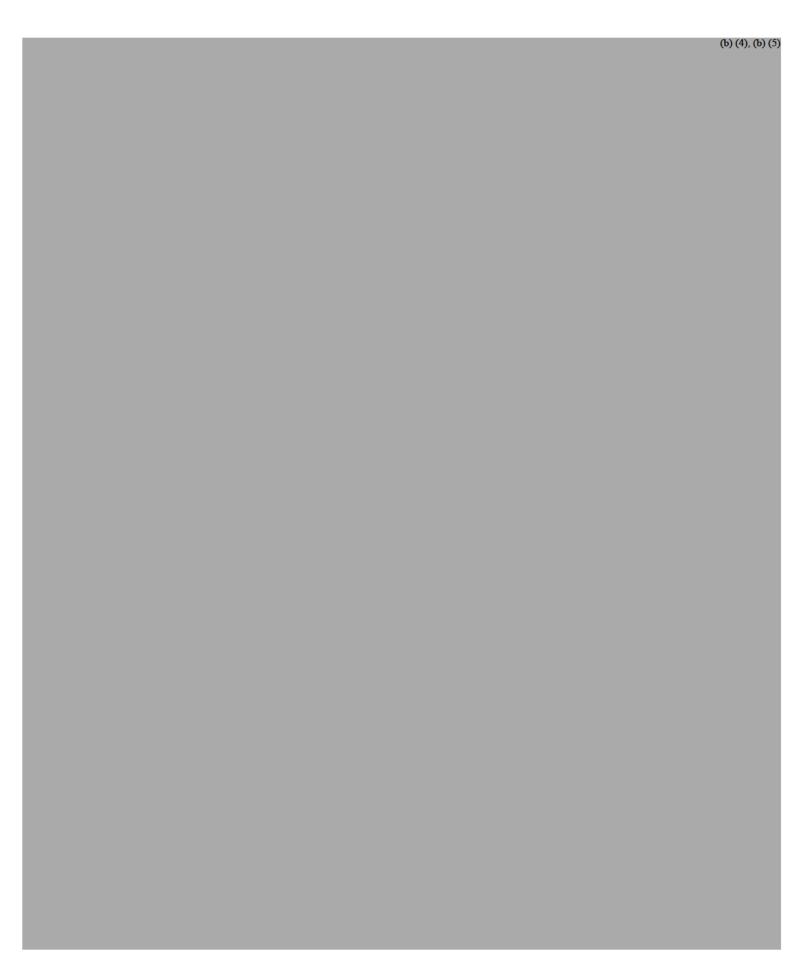
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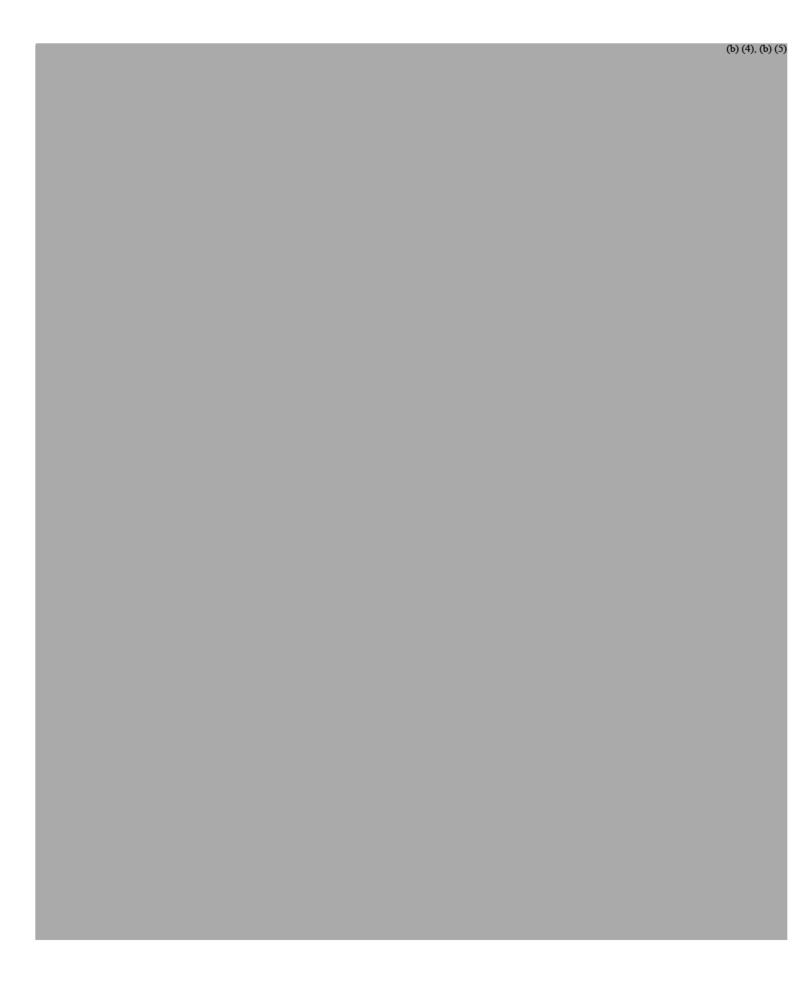
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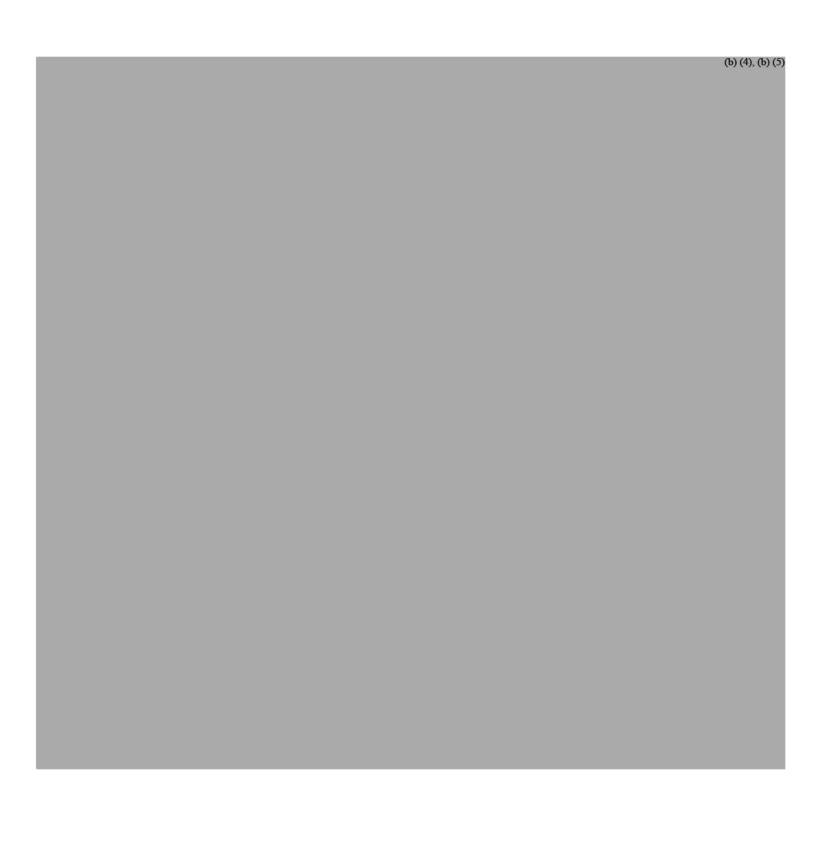


# ACCELERATING MEDICINES PARTNERSHIP (AMP) PROGRESS REPORT

Report to the AMP Executive Committee; as of August 26, 2016 (b) (4), (b) (5)







From: Wholley, David (FNIH) [T]

**Sent:** Mon, 24 Oct 2016 15:42:03 -0400 **To:** Collins, Francis (NIH/OD) [E]

Cc: Melencio, Cheryl (FNIH) [T];Gadbois, Ellen (NIH/OD) [E];Wood, Gretchen

(NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E] **Subject:** AMP Executive Committee Telecon -- October 28, 2016

### Dear Colleagues:

I have heard from FNIH that none of you will be able to attend our next AMP EC meeting this Friday, and have noticed it has been increasingly difficult to align with your schedules for these calls over the last six months or so. I thoroughly enjoy our interactions and consider your input critical to the success of the partnership, but I also appreciate that you are extremely busy and am wondering if there may be a better way to engage you on AMP, particularly given the maturity of the partnership at this point.

Should we keep the concept of a one hour teleconference, but have them less frequently? If so, should we reduce the frequency to every two months? Once a quarter? Or is there another path here you'd suggest we follow?

Please let me know your thoughts on this.

Regards, Francis From: Melencio, Cheryl (FNIH) [T] on behalf of Wholley, David (FNIH) [T]

**Sent:** Tue, 16 Aug 2016 10:32:35 -0400

To: Buckholtz, Neil (NIH/NIA) [C];Canet-Aviles, Rosa (FNIH) [T];Carter, Robert (NIH/NIAMS) [E];Collins, Francis (NIH/OD) [E];Cuss, Francis;Decker, Mike;Dolsten, Mikael;Gadbois, Ellen (NIH/OD) [E];Hodes, Richard (NIH/NIA) [E];Hodge, Martin;Hoffmann, Steve (FNIH) [T];Hudson, Kathy (NIH/OD) [E];Katz, Stephen I. (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Lea, Allison (NIH/OD) [C];Lifton, Richard;Lundberg, Jan;Paltoo, Dina (NIH/OD) [E];Rodgers, Griffin (NIH/NIDDK) [E];Ryan, Laurie (NIH/NIA) [E];Serrate-Sztein, Susana (NIH/NIAMS) [E];Smith, Philip (NIH/NIDDK) [E];Spear, Nicole (FNIH) [T];Stein, Peter;Sutherland, Margaret (NIH/NINDS) [E];Terry, Sharon MA;Whitaker, Sanya (FNIH) [T];Wholley, David (FNIH) [T]

Cc: Boskent, Celeste (NIH/OD) [E];Bronson, Charlette (NIH/NIA) [E];Cappello, Elizabeth;Clark, Katie;Craver, Stephanie (NIH/NIAMS) [E];Doswell, Greta (NIH/OD) [E];Edmonds, Pamela;Gwaldis, Janice;Yuliya Ilchyk;McManus, Ayanna (NIH/OD) [E];Melencio, Cheryl (FNIH) [T];Meltzer, Sherry (NIH/NIAMS) [E];Morgan, Emily (FNIH) [T];Tanya Murza;NIHDirectorMeetings;Poole, Charlene (NIH/NIDDK) [E];Protasiewicz, Ann;Schulke, Hilda (NIH/OD) [E];Sheehan, Joan (NIH/NIA) [E];Walker, Paula (NIH/NINDS) [E];Wilkerson, Anita D. (NIH/NIDDK) [E];Wood, Gretchen (NIH/OD) [E];Zander, Debra;FNIH Central Account

Subject: AMP Executive Committee Teleconference -- August 26 Cancelled

Dear AMP Executive Committee members and Steering Committee Co-chairs:

It is August, and not surprisingly we have some key EC members who will not be able to make our call on August 26. We have decided therefore to **cancel our August 26 call**. FNIH will send a brief update by email on the various AMP research initiatives, and we will re-convene the EC on September 23.

Thank you for your understanding and support.

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health

### **Cheryl Melencio**

Executive Assistant, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | www.fnih.org
Direct (301) 402-4970 | Fax (301) 480-2752

Combined Federal Campaign (CFC) #29165

For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.



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From: Wholley, David (FNIH) [T]

**Sent:** Thu, 22 Sep 2016 11:15:24 -0400 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** a quick note for tomorrow morning's AMP EC call

Hi Francis:

For tomorrow's call:

For AMP PD, I will frame this as an update on the scientific consensus the group has reached rather than the "final final" proposal.

(b) (4)

Working group

co-chairs (David Stone of Merck and Clemens Scherzer of Harvard) have been told they need to keep to 15 minutes, then I think 5 minutes for Q&A from the EC members, then I will suggest the co-chairs leave the call so the EC can discuss. I don't think we want them on the phone for the RA/SLE discussion, which will follow immediately.

The RA/SLE compromise has been discussed between Bob Carter, Marty Hodge, and Steve Hoffmann.

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(b) (4) We hope we can give

some general indication of their reaction to the EC should that be appropriate.

AD and T2D updates should be brief.

Thanks, David

**David Wholley** 

Director, Research Partnerships

Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | fnih.org
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] on behalf of Wholley, David (FNIH) [T]

**Sent:** Thu, 27 Oct 2016 10:25:15 -0400

To: Buckholtz, Neil (NIH/NIA) [C];Canet-Aviles, Rosa (FNIH) [T];Carter, Robert (NIH/NIAMS) [E];Collins, Francis (NIH/OD) [E];Cuss, Francis;Decker, Mike;Dolsten, Mikael;Gadbois, Ellen (NIH/OD) [E];Hodes, Richard (NIH/NIA) [E];Hodge, Martin;Hoffmann, Steve (FNIH) [T];Hudson, Kathy (NIH/OD) [E];Katz, Stephen I. (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Lea, Allison (NIH/OD) [C];Lifton, Richard;Lundberg, Jan;Paltoo, Dina (NIH/OD) [E];Rodgers, Griffin (NIH/NIDDK) [E];Ryan, Laurie (NIH/NIA) [E];Serrate-Sztein, Susana (NIH/NIAMS) [E];Smith, Philip (NIH/NIDDK) [E];Spear, Nicole (FNIH) [T];Sutherland, Margaret (NIH/NINDS) [E];Terry, Sharon MA;Whitaker, Sanya (FNIH) [T];Wholley, David (FNIH) [T]

Cc: Boskent, Celeste (NIH/OD) [E];Bronson, Charlette (NIH/NIA) [E];Cappello, Elizabeth;Clark, Katie;Craver, Stephanie (NIH/NIAMS) [E];Doswell, Greta (NIH/OD) [E];Edmonds, Pamela;Yuliya Ilchyk;Kent, Bridgett (NIH/NIDDK) [C];McManus, Ayanna (NIH/OD) [E];Melencio, Cheryl (FNIH) [T];Meltzer, Sherry (NIH/NIAMS) [E];Morgan, Emily (FNIH) [T];Tanya Murza;NIHDirectorMeetings;Poole, Charlene (NIH/NIDDK) [E];Protasiewicz, Ann;Schulke, Hilda (NIH/OD) [E];Sheehan, Joan (NIH/NIA) [E];Walker, Paula (NIH/NINDS) [E];Wilkerson, Anita D. (NIH/NIDDK) [E];Wood, Gretchen (NIH/OD) [E];Zander, Debra;FNIH Central Account

Subject: AMP EC teleconference tomorrow morning is CANCELLED

Attachments: AMP EC Slides October 28 2016 Final.pdf, 2016-09-

23\_AMP\_EC\_Telecon\_minutes.pdf

Dear AMP EC members and SC co-chairs:

It appears some of our AMP Executive Committee members now have standing conflicts that prevent them from making our standard 8AM time slot on Fridays once a month. Since it appears we will be missing some key participants for this week's meeting we have decided to cancel this Friday's AMP Executive Committee call, scheduled for 8:00 AM EDT. Attached please find a slide deck summarizing the current status of AMP in its stead.

We would like to reconvene the EC in November but would like to propose some changes in the timing and frequency of the calls. It has been proposed that we change the time of the next scheduled call on Friday, November 18 from 8:00AM to 7:00 AM EDT, and then reduce the frequency of the EC calls to once every two months thereafter (i.e., 7AM on the last Friday of January, March, May, and so forth).

Is this possible? Can you please respond with your revised availability to Cheryl Melencio (<a href="mailto:cmelencio@fnih.org">cmelencio@fnih.org</a>)? Thank you for your understanding and commitment.

Regards, David Wholley

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | fnih.org
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds* industry standards.

### **Accelerating Medicines Partnership**

Core Executive Committee Update (in lieu of teleconference)

28 October, 2016





## Contents

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# AMP AD F2F Annual Meeting 2016



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# Foundation for the National Institutes of Health Accelerating Medicines Partnership Core Executive Committee Teleconference Meeting Minutes Friday, September 23, 2016 8:00 a.m.- 9:00 a.m. ET

#### Participants:

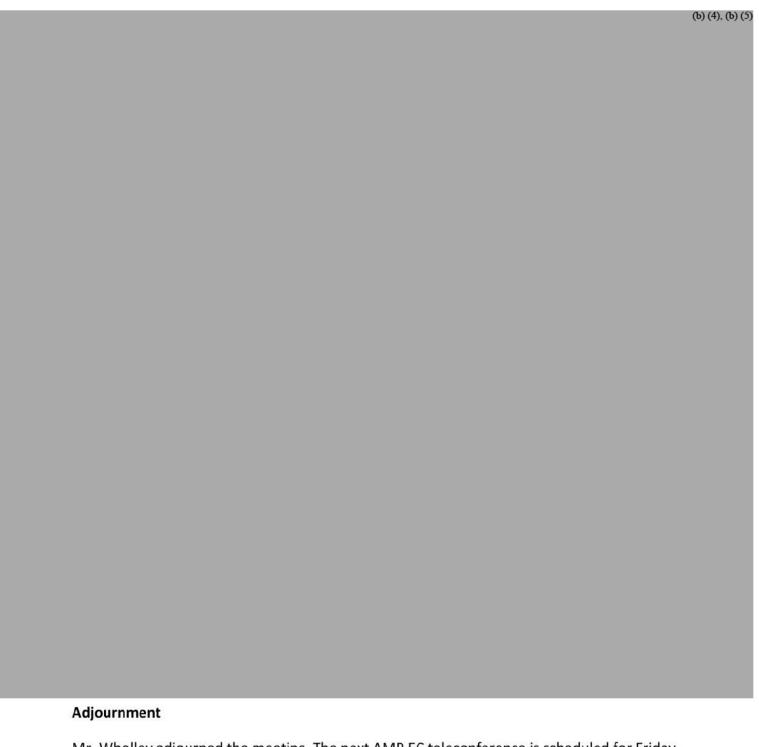
Neil Buckholtz (NIH/NIA), Rosa Canet-Aviles (FNIH), Robert Carter (NIH/NIAMS), Francis Collins (NIH/OD), Francis Cuss (BMS), Michael Decker (AbbVie), Michael Dolsten (Pfizer), Ellen Gadbois (NIH/OD), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Steve Katz (NIH/NIAMS), Allison Lea (NIH/OD), Dina Paltoo (NIH/OD), Griffin Rodgers (NIH/NIDDK), Laurie Ryan (NIH/NIA), Clement Scherzer (Harvard Medical School), Philip Smith (NIH/NIDDK), Susana Serrate-Sztein (NIH/NIAMS), Philip Smith (NIH/NIDDK), Nicole Spear (FNIH), Peter Stein (Merck), David Stone (Merck), Margaret Sutherland (NINDS), Sanya Fanous-Whitaker (FNIH), David Wholley (FNIH)



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Mr. Wholley adjourned the meeting. The next AMP EC teleconference is scheduled for Friday, October 28, 2016, from 8:00 am to 9:00 am ET.

**Sent:** Wed, 10 Aug 2016 19:52:16 -0400

To: Collins, Francis (NIH/OD) [E]

**Subject:** Automatic reply: PACT: Merck and AZ

I am out of the office on leave until Monday July 25 with limited access to email. Please contact Cheryl Melencio at cmelencio@fnih.org or 301-402-4970 if you have an urgent matter.

 Sent:
 Mon, 5 Sep 2016 13:19:28 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Subject: Automatic reply: PACT update and working group process

I am out of the office on leave until Wednesday September 7 and will return emails at that time.

**Sent:** Thu, 27 Oct 2016 12:14:03 -0400

To: Jan Lundberg; Cuss, Francis

**Cc:** debra.zander@bms.com;Edmonds, Pamela;Collins, Francis (NIH/OD) [E];Boskent, Celeste (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];Wood, Gretchen (NIH/OD)

[E]; Melencio, Cheryl (FNIH) [T]

Subject: December 16 AMP Extended EC call with other R&D leaders

#### Jan and Francis:

Sorry to bother you but in addition to the note just sent about rescheduling our EC calls I wanted to ask you specifically about the December Extended EC call, which is currently scheduled for 8-9:30 AM EST on Friday, December 16. Knowing that you both have standing appointments at 8AM on Fridays, I'd like to ask how likely it is that you might be able to move those for that particular date or whether we should try another time. The latter will not be easy given the number of schedules like yours we'd have to accommodate, but please let me know. As a reminder we sought the early hour for this in particular to accommodate our European-based colleagues. Thanks very much.

#### **David Wholley**

Director, Research Partnerships

Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | fnih.org
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.

**Sent:** Thu, 10 Nov 2016 12:37:29 -0500 **To:** Collins, Francis (NIH/OD) [E]

**Subject:** Do you have 2 minutes to chat one on one at the end of today's EC pre-call?

### **David Wholley**

Director, Research Partnerships

Foundation for the National Institutes of Health
9650 Rockville Pike | Bethesda, MD 20814 | fnih.org
Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.

**Sent:** Sun, 11 Dec 2016 11:13:40 -0500

To: Melencio, Cheryl (FNIH) [T];Collins, Francis (NIH/OD) [E];Dolsten, Mikael;Hoffmann, Steve (FNIH) [T];Spear, Nicole (FNIH) [T];Canet-Aviles, Rosa (FNIH) [T];Cuss, Francis;Lundberg, Jan;Carter, Robert (NIH/NIAMS) [E];Hodge, Martin;Ryan, Laurie (NIH/NIA) [E];Decker, Mike;Smith, Philip (NIH/NIDDK) [E];Gadbois, Ellen (NIH/OD) [E];Lea, Allison (NIH/OD) [E];Hudson, Kathy (NIH/OD) [E];Arrowchis, Leeanna (NIH/NIDDK) [C];Zander, Debra;Edmonds, Pamela;Protasiewicz, Ann;Boskent, Celeste (NIH/OD) [E];Doswell, Greta (NIH/OD) [E];Di Mantova, Emma (NIH/OD) [E];Morgan, Emily (FNIH) [T];NIHDirectorMeetings;Craver, Stephanie (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Sutherland, Margaret (NIH/NINDS) [E];Whitaker, Sanya (FNIH) [T];Wood, Gretchen (NIH/OD) [E];thomas\_melissa\_k@lilly.com

Subject: AMP Extended EC Dry Run slides

Attachments: AMP Ext EC Slides Dec 16 2016 DRAFT.pptx, 2016\_06\_27\_AMP EEC telecon

minutes final draft.docx

Dear AMP EC members and SC co-chairs: Please find attached the slides for our run-through tomorrow afternoon of the AMP Extended EC meeting, along with the minutes from the last EEC meeting in June. As a reminder logistics are copied below. Look forward to our discussion. David

When: Monday, December 12, 2016 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: (b) (6) Participant code: (b) (6) # Moderator code: (b) (6) Project Code

1191

In preparation for the December 16 AMP Extended EC Telecon

x

# Accelerating Medicines PartnershipExtended Executive Committee Update

16 December, 2016





# Today's meeting participants

## **Industry participants**

Michael DeckerJim Sulliva NIH abbyie

Biogen.

Spyros Artavanis-Tsakonas



Francis Cuss



Lon Cardon



Bill HaitJoe HedrickJames ListCat Oyler



Jan LundbergMelissa Thomas



Joseph Miletich



Mikael DolstenMarty Hodge



Elias Zerhouni



Salvatore Alesci

## Government participants



Francis CollinsEllen GadboisKathy HudsonAllison LeaDina PaltooLarry Tabak

Dan RotrosenEllen

Bob CarterStephen

Goldmuntz

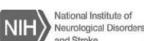




on Aging



National Institute of Diabetes and Digestive





Griffin RodgersPhilip Smith

Walter

Katz



and Kidney Diseases

Janet Woodcock

Sutherland

KoroshetzMargaret

## **Academic Participants**



Richard Lifton

## Non-profit participants



Maria CarilloJames



Alzheimer's **Drug Discovery** Foundation

Hendrix Howard Fillit



Sharon Terry



 Guy EakinAmanda Niskar



Helen NickersonMarlon

Pragnell



Leslie Hanrahan



Mary Collins



William Chin



Eryn MarchioloTeresa

#### Tarrant **Program Management**

David WholleyRosa Canet-AvilesSteve HoffmannNicole Spear



# Meeting Agenda

| 8:00 AM | Introduction   | Francis Collins, Mikael Dolsten |        |
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| 9:20 AM | Q&A Discussion | All (led by Collins/Dolsten)    |        |
| 9:30 AM | Adjourn        |                                 |        |





# **AMP Goals**

If successful, AMP will: Discover and validate new targets that companies can incorporate into their therapeutic development programsProvide new insights into known, existing targetsEnable a significant increase in our knowledge of tractable disease biology and disease pathwaysCreate a rich, comprehensive, integrated knowledgebase that is easy to use and available to the entire global research community ...for major common diseases.









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# Questions to consider:



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# Questions:























# Questions:





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### **Extended Executive Committee**

■ Next Meeting:AMP Extended Executive Committee: June 30, 2017 from 7:00am – 8:30 am Eastern US Time

# Foundation for the National Institutes of Health Accelerating Medicines Partnership (AMP) Extended Executive Committee (EEC) Teleconference Meeting Minutes

Monday, June 27, 2016

3:30 p.m. - 5:00 p.m. EDT

#### **Participants**

David Wholley (FNIH), Salvatore Alesci (Takeda), Spyros Artavanis-Tsakonas (Biogen), Neil Buckholtz (NIH/NIA), Rosa Canet-Aviles (FNIH), Robert Carter (NIH/NIAMS), Francis Collins (NIH/OD), Mary Collins (Alliance for Lupus Research, Lupus Research Institute), Francis Cuss (Bristol-Myers Squibb), Michael Decker (AbbVie), Mikael Dolsten (Pfizer), Guy Eakin (Arthritis Foundation), Ellen Gadbois (NIH/OD), Ellen Goldmuntz (NIH/NIAID), James List (Janssen), James Hendrix (Alzheimer's Association), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Allison Lea (NIH/OD), Eryn Marchiolo (Rheumatology Research Association), Joseph Miletich (Merck), Dina Paltoo (NIH/OD), Suzana Petanceska (NIH/NIA), Susana Serrate-Sztein (NIH/NIAMS), Philip Smith (NIH/NIDDK), Nicole Spear (FNIH), Peter Stein (Merck), Jim Sullivan (Abbvie), Margaret Sutherland (NIH/NINDS), Sharon Terry (Genetic Alliance), Janet Woodcock (FDA), Elias Zerhouni (Sanofi), Bill Chin (PhRMA), Walter Koroshetz (NIH/NINDS), Griffin Rodgers (NIH/NIDDK)

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## Adjourn

• Mr. Wholley announced that the next EEC meeting is scheduled for December 16, 2016, at 8 a.m. Eastern Time, and adjourned the meeting.



From: Melencio, Cheryl (FNIH) [T] on behalf of Wholley, David (FNIH) [T]

**Sent:** Fri, 16 Dec 2016 10:17:51 -0500

To: philipjust.larsen@sanofi.com;frank.nestle@sanofi.com;Buckholtz, Neil (NIH/NIA) [C];Canet-Aviles, Rosa (FNIH) [T];Carter, Robert (NIH/NIAMS) [E];Collins, Francis (NIH/OD) [E];Cuss, Francis;Decker, Mike;Dolsten, Mikael;Gadbois, Ellen (NIH/OD) [E];Hodes, Richard (NIH/NIA) [E];Hodge, Martin;Hoffmann, Steve (FNIH) [T];Hudson, Kathy (NIH/OD) [E];Katz, Stephen I. (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Lea, Allison (NIH/OD) [E];Lifton, Richard;Lundberg, Jan;Menetski, Joseph (FNIH) [T];Paltoo, Dina (NIH/OD) [E];Rodgers, Griffin (NIH/NIDDK) [E];Ryan, Laurie (NIH/NIA) [E];Serrate-Sztein, Susana (NIH/NIAMS) [E];Smith, Philip (NIH/NIDDK) [E];Spear, Nicole (FNIH) [T];Sutherland, Margaret (NIH/NINDS) [E];Tabak, Lawrence (NIH/OD) [E];Terry, Sharon MA;Thomas, Melissa;Wholley, David (FNIH) [T];Artavantis-Tsakonas, Spyros;Lon Cardon;Chin, Bill;Hait, Bill;Miletich, Joseph;Oyler, Cat;Plump, Andrew;Sullivan, Jim;Woodcock, Janet (FDA/CDER);Zerhouni, Elias;Alesci, Salvatore;Carrillo, Maria;Collins, Mary;Eakin, Guy;Fillit, Howard;Goldmuntz, Ellen (NIH/NIAID) [E];Sheri Grabus;Hanrahan, Leslie;Hedrick, Joe;Hendrix, James;Lappin, Debra;List, James;Marchiolo, Eryn;Jennifer McCulley;Nickerson, Helen;Niskar, Amanda;Pragnell, Marlon;Rigby, William F. C.;Rotrosen, Daniel (NIH/NIAID) [E];Tarrant, Teresa;Vallance, Patrick

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Subject: AMP Parkinson's Disease White Paper Attachments: AMP PD Integrated\_Proposal\_Final.pdf

## Dear AMP Extended Executive Committee Members:

As requested on our AMP update call this morning, please find attached the complete research "white paper" proposal for AMP Parkinson's Disease. Let me know if you have any questions or comments. Thanks

## David

David Wholley

Director, Research Partnerships

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9650 Rockville Pike | Bethesda, MD 20814 | fnih.org
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| For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards. |  |
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From: Wholley, David (FNIH) [T] Thu, 15 Sep 2016 21:21:56 -0400 Sent: Collins, Francis (NIH/OD) [E] To: Katz, Stephen I. (NIH/NIAMS) [E]; Carter, Robert (NIH/NIAMS) [E] Cc: AMP RA/SLE Program Milestone Discussion Subject: Francis: I know we are speaking tomorrow morning as part of our pre-call for next Friday's AMP EC call, but wanted to let you know that this past Tuesday afternoon the RA/SLE Steering Committee met by phone (b) (5) The criteria for the milestone as stated in the project plan is as follows: 1. The rate of sample acquisition in Phase 1 demonstrates feasibility of proceeding to Phase 2 within the proposed budget and timelines 2. The tissue-derived data is sufficiently robust to: a. Identify cells of the same type within and between samples b. Generate a significant disease-specific signature derived from single cells c. Establish the number of samples required to successfully execute Phase 2 Prior to Tuesday's SC call, the NIH and the investigator team had shared with the SC a comprehensive progress report which they felt showed that the project has indeed demonstrated the feasibility of acquiring and processing tissue samples for both lupus kidney and RA synovial biopsies and the ability to produce from those samples quality, reproducible data (CyTOF, scRNAseq) that includes disease-specific signatures. While the private sector stakeholders agreed that significant progress has been made, they asserted that they require access to raw data from ongoing Phase 1 analyses and time to complete independent internal analyses of the datasets in order to confirm the feasibility of continuing to Phase 2. (b) (5) The Phase 1 data will be made available to the partners in November, and the industry SC members said they should be able to complete their analyses before the end of this year. (b)(5)(b) (5)

(b) (5) but expect the issue will likely be

(b)(5)

discussed with the EC on that call regardless.

I am sure Steve Katz has additional context and perspective on this issue. I look forward to speaking with you tomorrow.

David

 From:
 Wholley, David (FNIH) [T]

 Sent:
 Fri, 12 Aug 2016 15:13:04 -0400

 To:
 Collins, Francis (NIH/OD) [E]

Cc: Baker, Rebecca (NIH/OD) [E];Rosema, Laura (NIH/OD) [E];Adam, Stacey (FNIH)

[T]

**Subject:** Email to invite academics

Attachments: PACT FC email to FA1 academics\_081016v3.docx, PACT FC email to FA2

academics\_081016v3.docx

Francis, while we are at it could you take a quick look at the email we drafted to invite academics onto the Working Groups, since we are mentioning your name (and Doug's)? They are designed to come from the co-chairs (we are still having some debate with the co-chairs in focus area 1 on the right academic invitees, but that should be cleared up shortly. If you are OK I will next send to the co-chairs, copying Doug, for their approval before we send them out...Thanks, David

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 From:
 Wholley, David (FNIH) [T]

 Sent:
 Fri, 16 Dec 2016 10:03:13 -0500

 To:
 Collins, Francis (NIH/OD) [E]

**Subject:** Extended EC - How did you think it went?

## **David Wholley**

Director, Research Partnerships

Foundation for the National Institutes of Health

9650 Rockville Pike | Bethesda, MD 20814 | fnih.org

Direct (301) 594-6343 | dwholley@fnih.org



For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] on behalf of Wholley, David (FNIH) [T]

**Sent:** Mon, 8 Aug 2016 16:49:11 -0400

To: Artavantis-Tsakonas, Spyros;Lon Cardon;Chin, Bill;Hait, Bill;Miletich, Joseph;Oyler, Cat;Plump, Andrew;Sullivan, Jim;Woodcock, Janet (FDA/CDER);Zerhouni, Elias;Alesci, Salvatore;Carrillo, Maria;Collins, Mary;Eakin, Guy;Fillit, Howard;Goldmuntz, Ellen (NIH/NIAID) [E];Hanrahan, Leslie;Hedrick, Joe;Hendrix, James;Lappin, Debra;List, James;Marchiolo, Eryn;Nickerson, Helen;Niskar, Amanda;Pragnell, Marlon;Rigby, William F. C.;Rotrosen, Daniel (NIH/NIAID) [E];Vallance, Patrick

Cc: Buckholtz, Neil (NIH/NIA) [C];Canet-Aviles, Rosa (FNIH) [T];Carter, Robert (NIH/NIAMS) [E];Collins, Francis (NIH/OD) [E];Cuss, Francis;Decker, Mike;Dolsten, Mikael;Gadbois, Ellen (NIH/OD) [E];Hodes, Richard (NIH/NIA) [E];Hodge, Martin;Hoffmann, Steve (FNIH) [T];Hudson, Kathy (NIH/OD) [E];Katz, Stephen I. (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Lea, Allison (NIH/OD) [C];Lifton, Richard;Lundberg, Jan;Paltoo, Dina (NIH/OD) [E];Rodgers, Griffin (NIH/NIDDK) [E];Ryan, Laurie (NIH/NIA) [E];Serrate-Sztein, Susana (NIH/NIAMS) [E];Smith, Philip (NIH/NIDDK) [E];Spear, Nicole (FNIH) [T];Stein, Peter;Sutherland, Margaret (NIH/NINDS) [E];Terry, Sharon MA;Whitaker, Sanya (FNIH) [T];Wholley, David (FNIH) [T]

**Subject:** Follow-up to June 27, 2016 AMP Extended Executive Committee teleconference Attachments: 2016\_06\_27\_AMP EEC telecon minutes FINAL.pdf, AMP June 27 2016 Extended EC follow up slides - August 2016.pptx

Dear Accelerating Medicines Partnership (AMP) Extended Executive Committee Members:

Please see attached the minutes from our last teleconference, on June 27. As noted in the minutes, there were two questions from EEC members that generated additional action items:



These were partly answered on the call, with requests that FNIH should send some supplemental information in each case. The attached PowerPoint slides address these requests. Please let me know if you have any further questions or comments, and thank you again for participating in AMP.

Regards,

David Wholley
Director, Research Partnerships
Foundation for the National Institutes of Health

## Foundation for the National Institutes of Health Accelerating Medicines Partnership (AMP) Extended Executive Committee (EEC) Teleconference Meeting Minutes

Monday, June 27, 2016

3:30 p.m. - 5:00 p.m. EDT

## **Participants**

David Wholley (FNIH), Salvatore Alesci (Takeda), Spyros Artavanis-Tsakonas (Biogen), Neil Buckholtz (NIH/NIA), Rosa Canet-Aviles (FNIH), Robert Carter (NIH/NIAMS), Francis Collins (NIH/OD), Mary Collins (Alliance for Lupus Research, Lupus Research Institute), Francis Cuss (Bristol-Myers Squibb), Michael Decker (AbbVie), Mikael Dolsten (Pfizer), Guy Eakin (Arthritis Foundation), Ellen Gadbois (NIH/OD), Ellen Goldmuntz (NIH/NIAID), James List (Janssen), James Hendrix (Alzheimer's Association), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Allison Lea (NIH/OD), Eryn Marchiolo (Rheumatology Research Association), Joseph Miletich (Merck), Dina Paltoo (NIH/OD), Suzana Petanceska (NIH/NIA), Susana Serrate-Sztein (NIH/NIAMS), Philip Smith (NIH/NIDDK), Nicole Spear (FNIH), Peter Stein (Merck), Jim Sullivan (Abbvie), Margaret Sutherland (NIH/NINDS), Sharon Terry (Genetic Alliance), Janet Woodcock (FDA), Elias Zerhouni (Sanofi), Bill Chin (PhRMA), Walter Koroshetz (NIH/NINDS), Griffin Rodgers (NIH/NIDDK)



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## Adjourn

• Mr. Wholley announced that the next EEC meeting is scheduled for December 16, 2016, at 8 a.m. Eastern Time, and adjourned the meeting.



Accelerating Medicines PartnershipFollow up to June 27, 2016 Extended Executive Committee Meeting

August 2016





















From: Wholley, David (FNIH) [T]

**Sent:** Mon, 15 Aug 2016 14:33:05 -0400

To: Collins, Francis (NIH/OD) [E]

Cc: Boskent, Celeste (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Di Mantova, Emma

(NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]

Subject: Friday August 26 AMP EC call

Francis, as usual we have been monitoring prospective attendance for the EC meeting at the end of this month. So far we will be missing Mikael Dolsten (driving his daughter to college) and Francis Cuss (on a plane). Everyone else seems to be OK so far. Please let me know how you would like to approach this. Thanks, David

From: Wholley, David (FNIH) [T]

**Sent:** Thu, 17 Nov 2016 20:30:34 -0500 **To:** Collins, Francis (NIH/OD) [E]

Subject: Fw: AMP PD solution schematic slide.pptx
Attachments: PD amp for exec meeting wjk short.pptx

FYI. Confidentially it looks like I may need your help on tomorrow's call to temper Walter's enthusiasm for so many slides for the Extended EC presentation...I suggested he ask the group about parameters for this. Thanks

Sent from my BlackBerry 10 smartphone.

From: Koroshetz, Walter (NIH/NINDS) [E] (b) (6)

Sent: Thursday, November 17, 2016 7:37 PM

To: Wholley, David (FNIH) [T]

Cc: Sutherland, Margaret (NIH/NINDS) [E]

Subject: RE: AMP PD solution schematic slide.pptx

Sounds good. The Call is at 7AM correct?

I worked on a draft slide set for the extended EC call on the 16<sup>th</sup>. See attached. Happy to get comments if wish to send around.

Walter

From: Wholley, David (FNIH) [T]

Sent: Thursday, November 17, 2016 3:26 PM

To: Koroshetz, Walter (NIH/NINDS) [E] (b) (6)

Subject: AMP PD solution schematic slide.pptx

Walter: I trust you will be on tomorrow morning's AMP Executive Committee call. We will be going over AMP PD at the front of the call---I will discuss funding status, but thought you could cover the attached slide (which is included in the materials we are sending out) that covers the science. We have a lot to go through however, so Francis asked if we could make sure we keep our section short—maybe 2 minutes on this slide. The EC got a full download on the scientific design on the last EC call from Marg Sutherland and Dave Stone, as you may remember, so this is in the nature of a short update. I am guessing we will ask you to repeat this as part of the December 16 Extended EC call (with all the pharma R&D heads). Thanks very much, David

















Back up slide